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In the Supreme Court of the United States

APOTEX, INC.,

Petitioner,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

CARMEN M. SHEPARD
KATE C. BEARDSLEY
Buc & Beardsley, LLP
919 18th Street, N.W.
Suite 600
Washington, D.C.
20006
(202) 736-3600

ROY T. ENGLERT, JR.*
MARK T. STANCIL
REBECCA S. LEGRAND
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP
1801 K Street, N.W.,
Suite 411
Washington, D.C. 20006
(202) 775-4500
renglert@robbinsrussell.com

**Counsel of Record*

QUESTION PRESENTED

Under the Hatch-Waxman Act, 21 U.S.C. §§ 301 *et seq.*, the first generic drug manufacturer to challenge a dubious patent claimed for a brand-name drug may be rewarded with a 180-day period within which only that company will be permitted to market a generic drug. As a practical matter, winning exclusivity for even a single generic can be worth hundreds of millions of dollars. In 2003, Congress responded to abuses of this provision by prescribing a series of "forfeiture events" that cause the generic manufacturer to lose such marketing exclusivity. Among other things, forfeiture is triggered when the challenged patent "is withdrawn by" the brand-name manufacturer or has "expired."

The D.C. Circuit held that, notwithstanding the absence of a textual limitation, forfeiture could not be triggered by "unilateral" action by the brand-name manufacturer. Relying on a prior decision interpreting the *pre*-2003 statutory scheme (and rejecting FDA's long-held position), the court of appeals concluded that such a limitation is required by the statute's "intended incentive structure." The question presented is:

> Whether a generic drug manufacturer may forfeit marketing exclusivity under 21 U.S.C. § 355(j)(5)(D) based on "unilateral" action by the holder of the challenged patent.

PARTIES TO THE PROCEEDING

The petitioner, plaintiff-appellant below, is Apotex, Inc.

The respondents, defendants-appellees below, are Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services; Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs; United States Food and Drug Administration; and United States Department of Health and Human Services, as well as Teva Pharmaceuticals, USA, Inc., intervenor-defendant-appellee below. Roxane Laboratories, Inc. was also a plaintiff-appellant below and is therefore a respondent under this Court's Rule 12.6.

RULE 29.6 STATEMENT

The ultimate parent of petitioner Apotex, Inc. is Sherfam Inc., which is not publicly traded. No publicly traded company owns 10% or more of the shares of petitioner or of any of its parent corporations.

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IMS Health & Generic Pharmaceutical Ass'n, *Savings Achieved Through the Use of Generic Pharmaceuticals 2000-2009* (July 2010) 20, 28

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JURISDICTION

The judgment of the court of appeals was entered on July 6, 2010. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant statutory provisions are set forth at App., *infra*, 107a-114a.

STATEMENT

This case involves the statutory scheme governing the generic drug industry. In 1984, Congress passed landmark legislation designed to foster the development of generic drugs as lower-cost alternatives to their brand-name equivalents. That effort was highly successful, giving rise to the multi-billion-dollar generic drug industry that benefits virtually every American today.

In 2003, with the generic industry firmly established, Congress amended the statute to facilitate

increased competition *among* generic manufacturers and thereby to drive drug prices down further. The amendments modified one of the statutory provisions designed to encourage generic manufacturers to challenge inappropriate patent claims made by a brand-name manufacturer hoping to stave off generic competition. That provision awarded the first generic manufacturer to bring such a challenge a period of market exclusivity during which only its product could compete with the brand-name product. Recognizing the significant costs that such an anti-competitive reward imposed on consumers, and questioning the continued need for such incentives, Congress amended the statute to enumerate no fewer than six circumstances in which a generic manufacturer would forfeit the period of market exclusivity.

In the decision that led to the decision below, the D.C. Circuit concluded that enforcing the plain language of those amendments would disrupt what the court of appeals believed to be the statute's "intended incentive structure." App., *infra*, 60a. Relying almost entirely on a prior circuit decision interpreting the *pre*-2003 version of the statute, the D.C. Circuit rejected FDA's contrary reading of the statute and held that a generic manufacturer's market exclusivity cannot be forfeited as a result of "unilateral" action by the brand-name manufacturer. App., *infra*, 62a-63a. That erroneous and textually ungrounded conclusion—besides rejecting the views of the expert agency—mangled a critical component of an indisputably vital federal statute, resulting in the imposition of literally billions of dollars in costs to health-care consumers that Congress never intended. Indeed, the government has rightly acknowledged

that this question is "exceptionally important." See *infra* p. 14.

A. The Statutory Framework

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the "Hatch-Waxman Act," regulates the FDA approval process for brand-name and generic drugs. A primary objective of the Act is "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. The Act established a framework designed to promote generic competition and speed the FDA approval process for generic drugs. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (the Hatch-Waxman Act allows drugs to be "marketed more cheaply and quickly"). In pursuing that larger goal, Congress balanced two sometimes competing considerations: (1) rewarding generic drug companies for challenging brand-name manufacturers' use of dubious patent claims to ward off generic competition; and (2) encouraging robust and rapid competition *among* generic drug companies to achieve the lowest possible price for consumers. In 2003, Congress amended the Act to recalibrate the balancing point between those objectives; this case turns on whether, in doing so, Congress should be taken at its word.

1. When seeking to introduce a new drug into the market, brand-name drug makers must submit a new drug application (NDA) to the FDA. The NDA must include detailed pharmacological and clinical information demonstrating that the drug proved safe and effective in a rigorous testing regimen, including human trials. 21 U.S.C. § 355(a),(b); see *Merck*

KGaA v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005). The NDA must also identify the number and expiration date for all patents that cover the new drug—*i.e.*, those patents that the manufacturer believes protect the new brand-name drug. 21 U.S.C. § 355(b)(1). Once an NDA is approved, FDA publishes that patent information in the "Approved Drug Products with Therapeutic Evaluations" book, 21 C.F.R. § 314.53(e), commonly known as the "Orange Book." So long as the patents listed in the Orange Book are valid and in force—and a would-be competitor cannot design around them—the brand-name manufacturer generally enjoys monopoly power in selling the new drug.

While recognizing that monopolistic rewards are sometimes necessary to encourage the development of new drugs, Congress also wanted to foster prompt competition by and among generic drug makers. Accordingly, the Hatch-Waxman Act significantly streamlined the generic drug approval process by authorizing abbreviated new drug applications (ANDAs) for generic drugs. See *Merck*, 545 U.S. at 196 n.1; *Eli Lilly*, 496 U.S. at 676. If the ANDA establishes that the generic drug is bioequivalent to an approved brand-name drug, the ANDA can rely on the same clinical safety and efficacy data used to support the brand-name drug NDA, which eliminates costly and time-consuming duplication of clinical studies. See *Eli Lilly*, 496 U.S. at 676; *Merck*, 545 U.S. at 196 n.1 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv), 355(j)(8)(B)).

ANDA applicants are required to review the patent information published in the Orange Book for the brand-name drug that the ANDA references. For

each listed patent, ANDA applicants must then certify: (I) that "such patent information has not been filed"; (II) "that such patent has expired"; (III) "the date on which such patent will expire"; or (IV) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii). These certifications are known by their respective paragraph numbers; this case principally concerns "paragraph IV" certifications.

2. If an ANDA contains a paragraph IV certification, the applicant must provide the brand-name drug maker with written notice setting forth the basis for that challenge. 21 U.S.C. § 355(j)(2)(B). The filing of a paragraph IV certification constitutes an act of patent infringement, 35 U.S.C. § 271(e)(2)(A), and the brand-name drug maker can therefore sue any such ANDA applicant to defend the validity or applicability of the disputed patent. 21 U.S.C. § 355(j)(5)(B)(iii). If the brand-name drug maker files suit within 45 days, approval of the ANDA is automatically stayed for 30 months to allow the completion of the litigation. *Ibid.*

Paragraph IV certifications are the primary means by which generic drug makers challenge potentially improper patents associated with brand-name drugs. The removal of improper patents from the Orange Book can result in earlier generic competition, ultimately reducing costs to consumers. See *Teva Pharmaceuticals, USA, Inc.* v. *Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA

holders in order to bring generic drugs to market earlier.").[1]

3. The Hatch-Waxman Act sought to encourage generic drug manufacturers to challenge questionable brand-name patents by rewarding the first ANDA applicant to file a paragraph IV certification for a given patent and drug (the "first applicant") with a 180-day period of generic market exclusivity. During that period, approval of any other ANDA for that same drug is delayed, and the first applicant alone is permitted to sell its generic version of the brand-name drug. Exclusivity is tremendously valuable; it allows the first applicant to offer a competing product for a brand-name drug that typically has a significant established market. Better still, because other generics cannot yet enter the market, the first applicant competes only with the brand-name manufacturer, allowing the generic to charge near-monopoly prices while still acquiring significant market share.[2]

That delay in full generic competition imposes substantial costs on consumers. See FTC, Prepared Statement Before the Senate Judiciary Committee (June 17, 2003) ("FTC Statement"), *available at* http://www.ftc.gov/os/2003/06/030617pharmtestimony

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[1] Suppose, for example, that a brand-name drug lists patents A, B, and C in the Orange Book. Suppose further that patents A and B squarely cover the brand-name drug but are set to expire in short order, whereas patent C is of dubious applicability or validity but has a more distant expiration date. A brand-name drug maker might list patent C in the Orange Book in hopes of delaying competition from generics.

[2] As explained in greater detail below (*infra* pp. 21-22), the first applicant's market advantages often linger well beyond expiration of the formal exclusivity period.

.htm) ("After the 180 days, subject to regulatory approvals, other generic companies can enter the market * * *. *Empirical research demonstrates that as additional generic competitors enter the market, generic prices decrease to lower levels, thus [benefiting] consumers.*") (emphasis added). The generic manufacturer with exclusivity can charge a much higher price as the lone competitor to the brand-name drug than it can once other generic manufacturers have entered the market.

4. Congress came to understand the costs that exclusivity, or duopoly, imposes on consumers. Experience under the original Hatch-Waxman Act showed that "brand and generic companies * * * abused [the 180-day] exclusivity period—both through collusive agreements and use of other tactics that allow the [exclusivity] provision to act as a bottleneck to generic competition." 149 Cong. Rec. S15,746 (daily ed. Nov. 24, 2003) (Sen. Schumer). In response, Congress in 2003 passed the Medicare Prescription Drug, Improvement, and Modernization Act (the "MMA"), which revised the 180-day generic exclusivity provisions to limit more tightly eligibility for exclusivity. 149 Cong. Rec. S15,884 (daily ed. Nov. 25, 2003) (Sen. Kennedy) (explaining that the MMA "restructure[s] how the 180-day generic exclusivity provisions work" by limiting eligibility for exclusivity); *id.* at S15,746 (Sen. Schumer) (the MMA recalibrates the balance between providing an incentive for generic applicants to challenge patents, and limiting the 180-day exclusivity award to "ensure[] that consumers have access to a low-cost generic as soon as possible").

The MMA enumerated six specific "forfeiture events" that will cause an otherwise eligible first applicant to lose its eligibility for exclusivity. 21 U.S.C. § 355(j)(5)(D). Two of those forfeiture events—"Failure to market" following the brand-name manufacturer's delisting of the patent from the Orange Book (§ 355(j)(5)(D)(i)(I)) and "Expiration of all patents" claimed by the brand-name manufacturer (§ 355(j)(5)(D)(i)(VI))—are at issue here.

a. *Patent delisting.* Full-scale litigation will not always be necessary to remove a challenged patent from the Orange Book. After a paragraph IV certification is filed, the brand-name manufacturer may ask FDA to "delist" the patent, effectively removing it as a barrier to generic competition. In enacting the MMA, Congress determined that such acquiescence would not result in exclusivity unless the first applicant can promptly bring the generic drug to market.

The relevant provisions of the MMA are densely worded but clear in application: If the patent as to which the first applicant has filed a paragraph IV certification is "withdrawn by the [brand-name manufacturer]," the first applicant forfeits exclusivity unless it brings the generic to market within the *longer* of (1) 75 days of delisting of the challenged patent or (2) the *earlier* of either 30 months from the date of the paragraph IV certification, or 75 days of final approval of the ANDA. 21 U.S.C. § 355 (j)(5)(D)(i)(I). Thus, even first applicants that do not bear the burdens of litigating a disputed patent are rewarded with exclusivity if they are able to move quickly enough in marketing the generic. Conversely, first applicants whose principal accomp-

lishment is winning a race to file an ANDA—but do not rapidly bring a drug to market—are not entitled to reap the massive benefits of exclusivity.

b. *Patent expiration.* The MMA also specified that a first applicant will not enjoy exclusivity if the challenged patent has expired. More particularly, the MMA states that the "180-day exclusivity period * * * shall be forfeited" when "[a]ll of the patents as to which the applicant submitted a [Paragraph IV] certification qualifying it for the 180-day exclusivity period have expired." 21 U.S.C. § 355(j)(5)(D)(i)(VI), (D)(ii). The statute does not limit forfeiture to expiration resulting from a particular cause.

This provision reflects FDA's "longstanding interpretation" of the Hatch-Waxman Act to require that, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished." App., *infra*, 19a; see *id.* at 20a ("The forfeiture provision at section 505(j)(5)(D)(i)(VI), enacted in the MMA, thus embodies the familiar principle that 180-day exclusivity does not survive patent expiration."). Numerous courts had upheld FDA's interpretation before the MMA's enactment. See, *e.g.*, *Dr. Reddy's Labs., Inc.* v. *Thompson*, 302 F. Supp. 2d 340, 357 (D.N.J. 2003); *Ranbaxy Labs., Ltd.* v. *Leavitt*, 469 F.3d 120, 126 n.* (D.C. Cir. 2006); *Ranbaxy Labs. Ltd.* v. *FDA*, 307 F. Supp. 2d 15, 19-20 (D.D.C. 2004), aff'd, 96 F. App'x 1 (D.C. Cir. 2004). Thus, the MMA forfeiture provisions codified FDA's conclusion that "permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute." App., *infra*, 25a.

B. Proceedings Below

Respondent Teva and petitioner Apotex are generic drug manufacturers and direct competitors. In 2003 and 2004, Teva filed ANDAs seeking FDA approval to market generic versions of two brand-name hypertension drugs—Cozaar and Hyzaar—manufactured by Merck. Both drugs contained the active ingredient losartan. Merck listed three patents in the Orange Book for both losartan drugs. Teva's ANDAs contained paragraph IV certifications for one of those patents: Patent No. 5,608,075 (the "'075 patent").[3] Apotex and several other generic manufacturers subsequently filed their own losartan ANDAs, and each of those ANDAs likewise contained a paragraph IV certification for the '075 patent. Merck elected not to sue any of the ANDA applicants for patent infringement. Merck ultimately requested that FDA delist the '075 patent from the Orange Book, which FDA did in April 2008.

1. *Teva* v. *Sebelius*

In June 2009, before FDA rendered a final decision on Teva's eligibility for exclusivity, Teva filed suit seeking to prevent FDA from enforcing the MMA's delisting forfeiture provision. Teva argued that the "delisting rule," which FDA had applied in agency decisions following enactment of the MMA,[4] was in excess of FDA's statutory authority and that

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[3] In addition to the '075 patent, Merck listed Pat. Nos. 5,138,069 and 5,153,197. Teva and Apotex both submitted paragraph III certifications for the latter two patents, listing the date on which the patents were set to expire.

[4] See FDA Acarbose Decision Letter (May 7, 2008) (FDA Docket No. 2007-N-0445); FDA COSOPT Decision Letter (Oct. 28, 2008) (FDA Docket No. 2008-N-0483).

Teva therefore had not forfeited its right to 180-day exclusivity by virtue of Merck's delisting of the '075 patent.

The district court disagreed and upheld FDA's reading of the statute. App., *infra*, 72a-106a. The patent delisting forfeiture event, the court explained, "is not ambiguous on its face": The text explicitly provides that an ANDA applicant forfeits exclusivity when it fails to market a drug after the relevant "'patent information * * * is withdrawn'" from the Orange Book. *Id.* at 98a-99a (quoting 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)). The court further held that, even if the MMA forfeiture provision could be "construed * * * to be ambiguous, the Court would be required to defer to the FDA's interpretation" of the statute because "FDA's interpretation of the statute is reasonable." *Id.* at 100a.[5]

The D.C. Circuit reversed. App., *infra*, 31a-71a.[6] The majority did not dispute that the MMA added "a

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[5] The district court denied Apotex's motion to intervene, concluding that Apotex's interests in the suit were too speculative at that time because FDA had not yet given Apotex's ANDA scientific approval. App., *infra*, 103a-105a. The district court permitted Apotex to appear as *amicus curiae*. *Id.* at 105a.

[6] Judge Henderson dissented, concluding that "the issue Teva seeks to litigate * * * will not be ripe unless and until [FDA] issues its final decision either granting or denying Teva's [ANDA]." App., *infra*, 67a. Apotex appealed the district court's denial of its motion to intervene and filed an *amicus* brief in the D.C. Circuit "express[ing] its substantive views of this case." *Id.* at 65a. The panel majority "considered" that brief "no less than if Apotex had formally intervened" in the district court but declined to resolve the intervention question under a "line of precedent in [the D.C. Circuit] declining to assess a would-be intervenor's standing when answering the question wouldn't affect the outcome of the case." *Ibid.*

critical new term to the statute: the 'forfeiture event.'" App., *infra*, 36a. Nor did it dispute that the statute declared that exclusivity "*shall* be forfeited by a first applicant" when it fails to market the generic drug within the specified time after the challenged patent "is withdrawn by the holder" (*i.e.*, the brand-name manufacturer). 21 U.S.C. § 355(j)(5)(D)(i)(I), (D)(ii) (emphasis added). Nevertheless, the panel concluded that FDA's reading of the statute "fails at *Chevron* step one"[7] because it deviated from the D.C. Circuit's "understanding of the statute's intended incentive structure." App., *infra*, 60a, 64a.

The court derived its understanding of that "incentive structure" principally from *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). That case addressed the impact of patent delisting under the *pre-MMA* statutory scheme—that is, *before* Congress enacted the patent delisting "forfeiture event." *Ranbaxy* rejected FDA's interpretation of the pre-MMA statute to eliminate the basis for an award of generic exclusivity when a brand-name manufacturer delisted a challenged patent if the generic had not already been sued by the brand. *Id.* at 123. In such circumstances, *Ranbaxy* held, forfeiture of exclusivity was "inconsistent with the structure of the statute," *id.* at 125, because it "diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book," *id.* at 126.

The *Teva* majority concluded that the MMA had done "nothing" to change the statutory incentive structure or to undermine the *Ranbaxy* decision.

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[7] See *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 842-843 (1984).

App., *infra*, 59a-60a. The court acknowledged FDA's contrary reading of the statute and purported to evaluate FDA's position "under the familiar two-part *Chevron* framework." *Id.* at 56a-57a. The court further acknowledged that FDA based its position on the MMA's addition of an explicit "forfeiture event" triggered by patent delisting and on the fact that "'the plain language of the statute contains no limitation on when delisting can occur.'" *Id.* at 58a (quoting *Teva* FDA Br. 44 (D.C. Cir. Oct. 16, 2009)). But the court concluded that Congress could not have meant to allow the brand-name manufacturer to "unilaterally deprive the generic of its exclusivity" by voluntarily delisting the challenged patent. *Id.* at 62a.

The court dismissed FDA's "argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate delisting requests," because "[p]recisely the same could have been said of the version of the statute that *Ranbaxy* addressed." App., *infra*, 62a. The court further claimed that brand-name manufacturers would voluntarily delist patents only when doing so would be "destructive" toward the statute's goal of encouraging generic competition. App., *infra*, 62a-63a. In the court's view, brand-name manufacturers would not delist a challenged patent to prevent claims of anti-competitive conduct or to avoid the expense or uncertainty of full-scale litigation (or for any other reason); rather, they would do so (and thereby expedite their own competition with *all* generic manufacturers) to discourage the filing of paragraph IV certifications with respect to future drugs. *Ibid.*

FDA petitioned for panel rehearing and rehearing *en banc*. FDA argued that the majority opinion in *Teva* was "fatally flawed because it condemns [FDA] for applying [the MMA's] explicit wording" and for heeding "Congress's finding that [180-day exclusivity under the pre-MMA statutory scheme] was being misused to thwart full competition." *Teva* FDA Reh'g Pet. (D.C. Cir. Apr. 5, 2010); see also *id.* at 3 ("The panel's * * * interpretation of the statute is not only contrary to the unambiguous text and Congress's deliberate rebalancing of competing goals, it squarely conflicts with this Circuit's message in other FDA decisions concerning the importance of fidelity to Congress's enactments."). FDA noted that, "[b]ecause all Hatch-Waxman cases can be filed in this Circuit (and most usually are), the panel majority's decision could be the last word on the substantial issues involved here." *Id.* at 15. Accordingly, FDA explained, the case was "exceptionally important" and "satisfie[d] the rigorous standards for *en banc* review." *Id.* at 3, 15. The D.C. Circuit denied the petition.

2. *Proceedings On Remand And Expiration Of The '075 Patent*

Shortly after the panel's decision, the parties discovered that the '075 patent had actually *expired* in March 2009 as a result of Merck's failure to pay the necessary maintenance fees to the Patent and Trademark Office. Teva then sought an order in the district court declaring that *neither* delisting nor expiration of the '075 patent had caused Teva to forfeit exclusivity. *Teva* Opp. to Motion To Amend Judgment at 4 (D.D.C. Mar. 23, 2010). Teva argued that the D.C. Circuit's opinion meant that any

"unilateral" action by the brand-name manufacturer resulting in removal of the challenged patent from the Orange Book could not affect the first applicant's right to exclusivity. The district court, however, concluded that the impact of patent expiration must be litigated "in a new lawsuit" filed after FDA had reached a decision directly addressing the impact of patent expiration. *Teva* Order Amending Judgment at 3 n.4 (D.D.C. Mar. 26, 2010).

The same day, FDA issued its decision addressing the expiration of the '075 patent—the decision directly at issue here. FDA first stated that, under the plain language of the statute as amended by the MMA, "patent expiration for any reason is a patent expiration forfeiture event." App., *infra*, 21a. "[P]ermitting the first applicant to retain exclusivity as to an expired patent," FDA explained, "requires FDA to take an action that is not sanctioned by the words of the statute." *Id.* at 25a. FDA thus declared that,

> if it were assessing this issue without reference to the *Teva* decision, it would find that, under the plain language of the statute, because the '075 patent will have expired by the time any ANDA referencing Cozaar or Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity.

Id. at 26a. FDA concluded, however, that the *Teva* decision precluded the forfeiture of exclusivity based on unilateral action by the brand-name manufacturer resulting in the removal of a challenged patent from the Orange Book. FDA therefore determined that, "consistent with the reasoning of the Court of Appeals, despite having been delisted by the patent

owner and having expired, the '075 patent nevertheless must be considered to remain a basis for 180-day exclusivity." *Id.* at 28a. Teva's exclusivity was set to begin on April 6, 2010.

3. ***Apotex* v. *Sebelius***

Four days after FDA issued its decision, Apotex and Roxane Laboratories filed suit in the United States District Court for the District of Columbia challenging the award of exclusivity to Teva. On April 2, 2010, the district court denied Apotex's motion for a preliminary injunction. App., *infra*, 4a-11a. The district court upheld FDA's conclusion that, despite the plain language of the MMA's forfeiture provisions, FDA was bound by the majority opinion in *Teva* to grant exclusivity to Teva. See *id.* at 9a ("The Court cannot find that the FDA was arbitrary or capricious when it politely expressed its disagreement with a D.C. Circuit decision * * * but nonetheless applied the reasoning of the Circuit to a different but, on these facts, closely related question.").

Apotex appealed and filed an emergency motion to stay the impending commencement of Teva's exclusivity period. The D.C. Circuit denied the motion, and Teva's exclusivity period began as ordered by FDA. On July 6, 2010, the D.C. Circuit issued a *per curiam* judgment affirming the district court's decision. App., *infra*, 1a-3a. Relying almost exclusively on *Teva*, the court of appeals reaffirmed its view that, in light of the statute's perceived "incentive structure," "Congress *could not* have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in

a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute." App., *infra*, 2a-3a (emphasis added).[8]

REASONS FOR GRANTING THE PETITION

This Court's immediate review is necessary to remedy fundamental and costly errors inflicted by the decision below. The Hatch-Waxman Act, as amended by the MMA, is largely responsible for the development of the multi-billion-dollar generic drug industry and the resulting benefits to health-care consumers. The 180-day exclusivity period is a key fulcrum point in the statutory scheme: Congress balanced that lucrative reward for first applicants with the need to promote full-scale competition *among* generics. Responding to anti-competitive abuses, the MMA adjusted that delicate equilibrium to limit more tightly the availability of exclusivity.

In ignoring that clear congressional command, the decision below did serious damage to a federal statute of the highest importance. In concrete terms, the decision below will confer massive anti-competitive advantages on drug companies (both generic and brand-name) that Congress did not authorize. In just the next several years, numerous major generic drugs are set to enter the market. If they do so under the erroneous decision below, consumers will bear

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[8] Teva's exclusivity period concluded on October 4, 2010. As the government acknowledged in seeking *en banc* review in the D.C. Circuit in *Teva*, that is no obstacle to further appellate review. See *Teva* FDA Reh'g Pet. 15 n.7 ("Even [in the event the exclusivity period has expired], the Court should rehear this matter under the 'capable of repetition, yet evading review' exception to the mootness doctrine.") (quoting *Del Monte Fresh Produce Co.* v. *United States*, 570 F.3d 316, 322-323 (D.C. Cir. 2009)).

billions of dollars in unnecessary and unintended costs.

Its practical importance aside, the D.C. Circuit's decision is plainly wrong as a matter of statutory interpretation. It does not seriously confront the statutory text, relying instead on the court's understanding of the statute's "intended incentive structure." It also errs in divining those "incentives," relying on a *pre*-MMA decision and, in turn, on the deeply flawed premise that brand-name manufacturers will work to frustrate the availability of generic exclusivity. The D.C. Circuit simply misunderstood that any manufacturer will prefer government-protected duopoly to wide-open competition.

Equally troubling, the D.C. Circuit did all of this under the guise of *step one* of *Chevron*, rejecting FDA's view that the statute draws no distinction between "unilateral" action and other action resulting in removal of a challenged patent from the Orange Book. This Court's immediate review is necessary to remedy these fundamental errors and the resulting damage to a vital federal statutory scheme.

I. The Question Presented Is Tremendously Important To The Generic Drug Industry And To Health-Care Consumers Nationwide

As the government has noted, the issue presented here is "exceptionally important." *Teva* FDA Reh'g Pet. 3. In practical terms, it controls the fate of billions of health-care dollars. If left undisturbed, the decision below will benefit brand-name manufacturers, who want nothing more than to see a first applicant win exclusivity and thereby delay full-scale competition with multiple generic manufacturers. It will also richly reward the generic manufacturer who wins a race to file a paragraph IV certification but is unable promptly to bring the generic drug to market.

What is more, first applicants have quickly learned how to leverage the initial exclusivity period into sustained market advantages that further impair full competition. The costs of delaying and then stifling full-scale generic competition are inevitably borne by health-care consumers. That is why Congress restricted the availability of exclusivity in the MMA, and that is why the D.C. Circuit's willingness to ignore that express congressional command warrants this Court's immediate review.

Enforcing the statutory scheme governing the generic drug industry is a matter of nationwide importance. Before the Hatch-Waxman Act's passage in 1984, generic drugs accounted for only about 12% of all prescriptions filled in the United States. See FDA, Greater Access to Generic Drugs (Jan. 2006) ("FDA Generics Report"), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm. Today, by contrast, about 75% of all U.S. prescriptions are filled with generic drugs (not to mention over-the-counter generics), and domestic sales of generic drugs average more than $50 billion per year. Jonathan D. Rockoff, *Prescription-Drug Sales Rise 5.1%*, Wall Street Journal, Apr. 2, 2010; Generic Pharmaceutical Ass'n, *Facts at a Glance*, *available at* http://www.gphaonline.org/about-gpha/about-generics/facts (last visited Sept. 27, 2010). Annual sales of a single blockbuster generic drug can exceed $1 billon.[9] The industry has flourished largely because Congress and FDA have established, monitored, and revised a comprehensive statutory

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[9] Sales for the generic form of the heartburn medicine Prilosec, for example, exceeded $1.1 billion in 2009. See "omeprazole" at Drug Topics, *2009 Top 200 Generic Drugs by Retail Dollars* (June 17, 2010), *available at* http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard/drugtopics/252010/674976/article.pdf.

and regulatory regime encouraging its development in the public interest.

The success of that venture has had profoundly positive consequences for virtually every American. Generic drugs generally cost a fraction of the price for the equivalent brand-name drug and thus "play a key role in making health care more affordable." FDA Generics Report. A recent study reported that generic drugs "saved the nation's health care system more than $824 billion dollars" over the last ten years, with savings of $139.6 billion in 2009 alone. IMS Health & Generic Pharmaceutical Ass'n, *Savings Achieved Through the Use of Generic Pharmaceuticals 2000-2009* at 1 (July 2010) ("IMS Report"), *available at* http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010_0.pdf.

The 180-day exclusivity period is a crucial—and carefully calibrated—facet of the statutory scheme fostering generic competition. See FTC Statement ("The second significant component of Hatch-Waxman is the '180-day period of exclusivity.' * * * Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternatives to patented drugs."). Exclusivity offers generic manufacturers an incentive to challenge dubious patents listed by brand-name manufacturers in the Orange Book, thus encouraging the earlier introduction of generic drugs. But exclusivity is also *anti*-competitive, because "the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher generic price until more generic products enter)." *Ibid.* Understanding the tremendous rewards at stake is necessary to appreciate fully the magnitude of the D.C. Circuit's error in rejecting Congress's choice to pre-

scribe a specific balance between those contending objectives.

Winning a 180-day exclusivity period for even a single drug may be "worth several hundred million dollars" to a generic manufacturer. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006). That is because the generic manufacturer must compete only with the brand-name manufacturer (and vice versa), resulting in markedly higher duopoly pricing during the exclusivity period. Indeed, it is well documented that the vast majority of the cost savings offered by generics emerge only when there is full competition between multiple generic manufacturers. FDA has reported that, "[o]n average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer"—about six percent. FDA, *Generic Competition and Drug Prices*, *available at* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm (last visited Sept. 27, 2010). "[T]he appearance of a second generic manufacturer," however, "reduces the average generic price to nearly half the brand name price. * * * For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." *Ibid.* Exclusivity thus gives the generic manufacturer a significant period of sales at artificially inflated prices.

What is more, the benefits of the 180-day exclusivity award often last well beyond the exclusivity period. That is due in part to the presence of pharmacy benefit managers (PBMs), which "play a critical role in managing prescription drug benefits," GAO,

Federal Employees' Health Benefits 1 (Jan. 2003), *available at* http://www.gao.gov/new.items/d03196.pdf, and other large-volume customers. For example, PBMs are hired by health-care plans to develop an approved list of drugs for plan participants and to negotiate with drug manufacturers to supply those drugs. These contracts are usually long-term, often running for two or three years. A manufacturer that is the exclusive source of a newly available generic drug thus has the opportunity to become the PBMs' supplier for far longer than the initial 180 days. And the generic manufacturer is also likely to use that leverage to become the PBMs' supplier for *other* generic drugs. Accordingly, "the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants." *Mova Pharmaceutical Corp.* v. *Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (internal quotation marks omitted).

Exclusivity is good news for brand-name manufacturers, too. See Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. & TECH. L. REV. 175, 190 (2007) ("the grant of exclusivity * * * also provides a substantial benefit to the branded pharmaceutical maker"). The higher the price charged by the generic manufacturer, the less downward price pressure the brand-name manufacturer faces. Almost any delay in reckoning with competition from multiple generic manufacturers results in more dollars for brand-name manufacturers. As explained in more detail below (*infra* pp. 32-34), the D.C. Circuit failed to appreciate this basic point, but the economic reality is inescapable: Exclusivity for one generic manufactur-

er means a much softer landing for the brand-name manufacturer.

These costs, of course, are ultimately borne by health-care consumers in the form of higher drug prices. Evidence suggests that awarding market exclusivity for a single, widely prescribed drug can leave consumers with a tab running into the billions of dollars. One commentator has estimated that a one-year delay in the entry of generic competition for certain widely prescribed drugs "represents, under conservative assumptions, a transfer from consumers to producers of about $14 billion." C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 650 (2009). Because duopoly pricing exists during the 180-day exclusivity period, and such prices are (by FDA's estimate) only six percent lower than the brand-name monopoly price, the costs to consumers are massive. See also Medco, *2010 Drug Trend Report* 6, *available at* http://www.drugtrend.com/art/drug_trend/pdf/DT_Report_2010.pdf (last visited Sept. 27, 2010) ("In recent years, 6-month exclusivity in generic marketing (which keeps generic prices temporarily high) has tempered the rate at which plan sponsors realize the full savings potential" of shifting patients to generic drugs.).

Because exclusivity is such a rich reward, it is a crucial lever in the larger statutory scheme encouraging full generic competition. Accordingly, when experience under the original Hatch-Waxman Act showed the potential for abuse of the exclusivity provisions and highlighted the steep costs exclusivity can impose on consumers, Congress deliberately

pared back its availability in the MMA. Indeed, some questioned whether exclusivity should be eliminated altogether, because the now-powerful generic drug industry no longer needed such strong incentives to challenge brand-name drug manufacturers. See 148 Cong. Rec. S7,349 (daily ed. July 25, 2002) (Sen. Hatch) ("Frankly, I think we need more public discussion and debate about the wisdom of retaining—lock, stock, and barrel—the old 180-day exclusivity award."). In the end, Congress decided to enumerate specific "forfeiture events" that limit a first applicant's entitlement to exclusivity. The decision below ignores that deliberate legislative choice and thus disrupts this carefully calibrated statutory scheme

II. The Issue Is Recurring And Warrants Immediate Review

The availability of generic exclusivity in the wake of "unilateral" action by a brand-name manufacturer to remove a challenged patent from the Orange Book is a recurring question that merits this Court's immediate review. Generic manufacturers continue to file paragraph IV certifications in large numbers, and brand-name manufacturers continue to delist challenged patents rather than face allegations of anti-competitive conduct or costly patent litigation. And, as the government has acknowledged, the decision below is almost surely the *de facto* final word on the subject. Delaying resolution of this question will force consumers to bear billions of dollars in costs that Congress never intended.

This issue has arisen repeatedly in recent years, and the decision below will have widespread effect if left undisturbed. Under the pre-MMA statutory

scheme, FDA refused to award exclusivity to first applicants when the challenged patent had been delisted without litigation. FDA applied that rule on numerous occasions and to many significant drugs. See FDA Ranbaxy Decision Letter 18-19 (Oct. 24, 2005) (FDA Docket No. 2005-P-0008) (explaining that FDA had already "delisted patents for Paxil (paroxetine hydrochloride), Serzone (nefazadone), Zyprexa (olanzapine), and Detrol (tolterodine)"). In just the few years since the MMA's enactment, FDA has addressed the impact of patent delisting on exclusivity for four major brand-name drugs where the manufacturer "unilaterally" caused the removal of a challenged patent from the Orange Book. Those drugs alone represent nearly two billion dollars in annual sales.[10]

Many more are coming down the pike: By our count, there are 27 patents for brand-name drugs—including several blockbusters—for which ANDAs including paragraph IV certifications have been filed and the challenged patent has been delisted or allowed to expire. See Apotex Reply to Opp. to Motion For Prelim. Inj. at 8 & n.3 (D.D.C Apr. 1,

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[10] FDA determined, for example, that patent delisting forfeited generic exclusivity for the glaucoma drug COSOPT, which had annual sales of approximately $337 million, and for the diabetes drug Precose, which had annual sales of approximately $34 million. See CVS/Caremark, *Generic Prospective Pipeline Summary* (June 12, 2009), *available at* http://www.khpa.ks.gov/sehp/download/BenDescr2009/2009GenPipelineSum.pdf.
Hyzaar and Cozaar, the two brand-name losartan drugs at issue here, have combined annual sales of approximately $1.6 billion. See Teva press release (Apr. 9, 2010), *available at* http://www.medicalnewstoday.com/articles/184871.php (citing IMS sales data).

2010). Some of these arise under the pre-MMA statute, which governs ANDAs filed before 2003,[11] but most are subject to the MMA's forfeiture provisions. If the decision below is allowed to stand, FDA will have no choice but to award exclusivity in many of these cases in spite of its wholly correct, and deference-worthy, conclusion that the statute does not authorize it.

The D.C. Circuit and the district court—which reached opposite conclusions—are the only courts to have addressed this issue, but that is neither surprising nor a reason to delay review. As the government has correctly acknowledged, because "all Hatch-Waxman cases can be filed in [the D.C. Circuit] (and most usually are), the panel majority's decision could be the last word on the substantial issues involved here." *Teva* FDA Reh'g Pet. 15. Indeed, the government understated the matter slightly to note that the D.C. Circuit is "the usual forum for these disputes," *id.* at 3. The D.C. Circuit has decided 11 cases concerning FDA's interpretation of the Hatch-Waxman Act's 180-day generic exclusivity provision. Only one published case from another circuit directly addresses FDA's interpretation of the 180-day exclusivity provision, *Mylan Pharmaceuticals, Inc.* v. *FDA*, 454 F.3d 270, 271 (4th Cir. 2006), and that

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[11] Even those drugs still governed by the pre-MMA statute will potentially benefit from a reversal of the decision below. While the most obvious problem with the court of appeals' analysis is its rejection of the plain text of the MMA's forfeiture provisions, the court was also wrong to claim that the *pre*-MMA "incentive structure" required the award of exclusivity in these circumstances.

opinion closely tracks a related D.C. Circuit decision.[12]

What is more, the D.C. Circuit's conclusion that Teva's lawsuit seeking a declaration of its entitlement to exclusivity before FDA had rendered a final decision was ripe likely will give first applicants the means to file any such future actions in D.C. to take advantage of this rule. By contrast, it is unclear whether a generic competitor of the first applicant would be able to bring suit elsewhere—here, the district court denied Apotex's attempt to intervene in Teva's lawsuit because FDA had not yet granted Apotex tentative approval to market the drug, and the D.C. Circuit declined to address that issue on appeal. It is thus exceedingly unlikely that a split will develop on this issue.

Meanwhile, the meter is running. The Federal Trade Commission estimates—conservatively—that products with roughly $90 billion dollars in sales were subject to live paragraph IV challenges at the end of 2008. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 9 (Jan.

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[12] The Federal Circuit also considers Hatch-Waxman issues from time to time when those issues arise in patent litigation, but the Federal Circuit generally cannot address claims regarding Hatch-Waxman statutory construction and FDA rulemaking. See, *e.g.*, *Minnesota Mining & Mfg. Co.* v. *Barr Labs., Inc.*, 289 F.3d 775, 783 n.4 (Fed. Cir. 2002) (refusing to resolve claims seeking "improper judicial enforcement of the provisions of the Hatch-Waxman Amendments, outside of the context of an APA suit"). The Federal Circuit did address FDA rules regarding Orange Book listings in *Apotex, Inc.* v. *Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), but in that case the court simply upheld FDA's policy of refusing to review Orange Book listings independently.

2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. Another report estimates that "[d]rugs with total 2009 U.S. sales of about $50 billion could lose patent protection over the next 3 years, expanding in an almost unprecedented manner the market for lower-cost generics." Medco, *supra*, at 42. Some of these are truly blockbuster drugs: "Six of the 10 current largest-selling drug products are expected to encounter generic competition" in the next few years "including the top two: Pfizer's $14 billion cholesterol fighter Lipitor® and the blood clot preventer Plavix® by Bristol-Myers Squibb." IMS Report at 3-4. This Court's immediate review is therefore necessary to avoid the billions of dollars in costs associated with the erroneous award of exclusivity with respect to even one of these drugs.

This Court has not hesitated to grant certiorari where, as here, it confronts issues that "concern the construction of a major federal statute." *United States* v. *Donovan*, 429 U.S. 413, 422 (1977). Certiorari is often granted even in the absence of a circuit split when a court of appeals fumbles a question of first impression regarding the interpretation of a federal statute. See, *e.g.*, *Household Credit Services, Inc.* v. *Pfennig*, 541 U.S. 232, 235 (2004); *American Federation of Musicians* v. *Wittstein*, 379 U.S. 171, 175 (1964); see also EUGENE GRESSMAN ET AL., SUPREME COURT PRACTICE 267 (9th ed. 2007) (for many cases involving "the construction and application of acts of Congress * * * the importance of the issue is the major basis for securing review"). On a federal statutory issue of such profound importance and widespread concern, it is both unnecessary and ill advised to delay review.

That is especially true because, as we briefly explain below, the D.C. Circuit got this question dead wrong.

III. The Decision Below Is Erroneous

Three errors in the court of appeals' analysis are particularly deserving of this Court's immediate review.

First and foremost, the D.C. Circuit failed to heed the most basic tenet of statutory interpretation that "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank* v. *Germain*, 503 U.S. 249, 253-54 (1992); see also, *e.g.*, *Carcieri* v. *Salazar*, 129 S. Ct. 1058, 1063 (2009). The MMA specifically identified patent delisting as a "forfeiture event" and gave no indication that it would not apply if that delisting was the result of "unilateral" action by the brand-name manufacturer. To the contrary, the text states explicitly that forfeiture is triggered if the patent is "withdrawn ***by*** the [brand-name manufacturer]." 21 U.S.C. § 355(j)(5)(D)(i)(I) (double emphasis added). A patent delisted "by" the brand-name manufacturer most naturally means one that is delisted "unilaterally." At the very least, it must *include* unilateral delisting.

The D.C. Circuit gave no meaningful consideration to that text. Rather, the court noted simply that it had already crossed this bridge in *Ranbaxy* and saw no reason to turn back:

> The argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate delisting requests fails. Precisely the same could have been said of the version of the statute that *Ranbaxy*

> addressed, and we nevertheless concluded that its structure precluded an FDA rule allowing the agency "to delist a patent upon the request of the [brand manufacturer]" when the delisting would rob the generic maker of earned exclusivity.

App., *infra*, 62a. But *Ranbaxy* concerned the *pre*-MMA version of the statute, before Congress expressly enumerated delisting as a forfeiture event without limitation. See *Mobil Oil Corp.* v. *Higginbotham*, 436 U.S. 618, 625 (1978) ("There is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted."). Accordingly, relying on *Ranbaxy* to settle the question of the *post*-MMA statute's plain language wholly misses the point.

The statute is equally clear on the effect of patent expiration. It declares that the "180-day exclusivity period * * * *shall* be forfeited," 21 U.S.C. § 355(j)(5)(D)(ii) (emphasis added), when "[a]ll of the patents as to which the applicant submitted a [Paragraph IV] certification qualifying it for the 180-day exclusivity period *have expired*," *id.* § 355(j)(5)(D)(i)(VI) (emphasis added). Yet again, there is no mention of *why* a patent has expired, much less a textual requirement that the patent must have expired of "natural causes" rather than by virtue of the holder's failure to pay the required fees. There is simply no basis in the text for the D.C. Circuit's holding that forfeiture does not occur if expiration is the result of "unilateral" action by the patent holder.

The D.C. Circuit not only ignored those clear textual commands but also failed to give serious

consideration to FDA's longstanding position that unilateral action can result in the forfeiture of exclusivity. While paying lip service to "the familiar two-part *Chevron* framework," App., *infra*, 57a, the court made no meaningful attempt to explain how the statute's text foreclosed FDA's position. Instead, the court again retreated to its pre-MMA decision in *Ranbaxy* and declared that it "s[aw] nothing in the [MMA] that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event." App., *infra*, 64a. "For that reason," the court concluded, FDA's position "fails at *Chevron* step one." *Ibid.* But relying on a previous interpretation of the "incentive structure" of a prior version of a statute is not the inquiry that *Chevron* step one demands. Cf. *Nat'l Cable & Telecomms. Ass'n* v. *Brand X Internet Servs.*, 545 U.S. 967, 980-986 (2005) (even an agency's own change of position requires fresh judicial inquiry about the meaning of a statute whose administration is entrusted to the agency).

The D.C. Circuit's terse dismissal of FDA's position is all the more remarkable because Congress intended the MMA to limit the availability of exclusivity. The MMA responded, in part, to evidence that "brand and generic companies * * * abused [the 180-day] exclusivity period." 149 Cong. Rec. S15,746 (daily ed. Nov. 24, 2003) (Sen. Schumer). How could the enumeration of specific "forfeiture events" not at least raise the specter of ambiguity as to whether "unilateral" delisting or expiration would trigger forfeiture? Indeed, Congress enacted the MMA *after* FDA had articulated its view that a brand-name manufacturer's delisting of a challenged patent—unilateral or otherwise—could forfeit the first

applicant's exclusivity. If Congress had intended the opposite, as the D.C. Circuit later concluded in *Ranbaxy* and again in the decisions below, Congress would have said so when promulgating the MMA. It did not, and the D.C. Circuit was wrong to "override that choice." *Whitfield* v. *United States*, 543 U.S. 209, 217 (2005). Indeed, as the D.C. Circuit would have it, Congress witnessed FDA *wrongly* interpreting the statute without regard to whether a delisting action was "unilateral" and then specifically enumerated no fewer than six "forfeiture events" without limiting them to non-unilateral conduct. That defies common sense; at the very least, it introduces a profound ambiguity into the statute and makes the D.C. Circuit's ruling on *Chevron* step one entirely implausible.

Even if the statute's "incentive structure" could somehow trump its plain text, the D.C. Circuit fundamentally misunderstood the operative economic realities. The D.C. Circuit believed that, under FDA's reading of the statute, brand-name manufacturers would deliberately "pull the rug from under the paragraph IV certification" as a way to combat generic competition. App., *infra*, 35a. Thus, the D.C. Circuit's theory goes, brand-name manufacturers view unilateral removal of a patent from the Orange Book as a way to *hinder* competition. That is wrong.

For starters, the D.C. Circuit's theory overlooks the obvious fact that removing a challenged patent—unilaterally or otherwise—*expedites* full generic competition for that drug. Here, for example, Merck's decision to allow the '075 patent to expire meant that it faced generic competition in sales of Cozaar and Hyzaar beginning in 2010 instead of 2014. For many

drugs, removal of the challenged patent will cost the brand-name manufacturer hundreds of millions of dollars in lost sales. And any discouraging effect such action might have on generic manufacturers would be, at best, indirect and delayed. The one sure result of "unilateral" delisting or expiration is that brand-name manufacturers will face full-on generic competition sooner.

In fact, if a challenged patent is to be removed from the Orange Book (whether by voluntary action of the brand-name manufacturer or for some other reason), brand-name manufacturers will very much hope that one generic manufacturer wins exclusivity. That is because, as explained above (*supra* pp. 22-23), the brand-name manufacturer stands to make significantly more money competing with just one generic than with many. Recall that prices tend to drop only about six percent off the brand-name monopoly price during the generic exclusivity period, but they plummet 80% when multiple generics enter the market. See *supra* p. 21. Brand-name manufacturers reap extraordinary benefits from the competition-limiting effects of exclusivity, so they are highly unlikely to participate in its untimely demise.

Brand-name manufacturers unilaterally seek removal of a challenged patent from the Orange Book, *not* to frustrate generic competition, but because there are other powerful incentives to do so. A principal driver is the fear of being charged with anti-competitive conduct for attempting to prolong the monopoly resulting from legitimate patents by also listing a bogus one. In recent years, the FTC has made significant efforts to punish companies for such

conduct.[13] As a result, when an ANDA applicant makes a paragraph IV certification challenging a listed patent, the brand-name manufacturer must take a long, hard look at whether its claim will withstand government scrutiny.

Even without fear of government action, brand-name manufacturers must consider the practical costs of asserting a bogus patent. There is little sense in such circumstances in spending millions of dollars to sue a generic manufacturer for infringement or to defend a declaratory judgment action by the generic manufacturer. If a patent has a truly weak connection to a brand-name drug, the brand-name manufacturer faces significant potential costs for maintaining it. The best course is often to seek its removal from the Orange Book, thus achieving precisely the result that Congress intended.

Finally, even if the D.C. Circuit were correct that preserving exclusivity automatically furthered the larger goal of promoting generic competition, that is not a reason to disregard the statute's plain language. It is axiomatic that "no legislation pursues its

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[13] See FTC Response to IVAX Citizen Petition 7 (Apr. 5, 2005) (FDA Docket No. 2005-P-0008) ("The Commission has brought a number of enforcement actions involving the improper listing of patents in the Orange Book by brand-name companies, which allegedly delayed generic drug approval and resulted in consumer harm."); FTC Statement ("Our 'second generation' of enforcement activities has involved allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings * * *."). Bristol-Myers Squibb and Biovail, for example, entered into consent agreements with the FTC in which they agreed, among other things, to cease listing improper patents in the Orange Book. *Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003); *Biovail Corp.*, 134 F.T.C. 407 (2002) (consent orders).

purposes at all costs." *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987) (per curiam). Rather, "[d]eciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Id.* at 526 (emphasis in original). Even if the anti-competitive effects that accompany generic exclusivity are merely short-term, it is up to Congress—not the courts—to decide how much encouragement to offer the generic drug industry. Indeed, there is overwhelming evidence that Congress has been particularly successful in this endeavor: In the quarter-century since the Hatch-Waxman Act was passed, generic drugs have proliferated and saved consumers billions of dollars, while brand-name manufacturers have continued to make groundbreaking and lifesaving discoveries. Courts have no business tinkering with such a carefully calibrated legislative balance.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

CARMEN M. SHEPARD
KATE C. BEARDSLEY
Buc & Beardsley, LLP
919 18th Street, N.W. Suite 600
Washington, D.C. 20006
(202) 736-3600

ROY T. ENGLERT, JR.*
MARK T. STANCIL
REBECCA S. LEGRAND
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP
1801 K Street, N.W. Suite 411
Washington, D.C. 20006
(202) 775-4500
renglert@robbinsrussell.com

**Counsel of Record*

OCTOBER 2010

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 10-5094 **September Term 2009**

1:10-cv-00517-RMC
1:10-cv-00521-RMC

Filed On: July 6, 2010

Apotex, Inc.,

Appellant

Roxane Laboratories, Inc., Civil Action No. 10-521,

Appellee

v.

Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, et al.,

Appellees

No. 10-5108

Roxane Laboratories, Inc.,

Appellant

v.

United States Food and Drug Administration, et al.,

Appellees

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

BEFORE: Tatel, Griffith, and Kavanaugh, Circuit Judges

JUDGMENT

These consolidated appeals were considered on the record from the United States District Court for the District of Columbia and on the briefs filed by the parties. *See* Fed. R. App. P. 34(a)(2); D.C. Cir. Rule 34(j). It is

ORDERED AND ADJUDGED that the district court's order filed April 2, 2010, denying motions for a preliminary injunction, be affirmed. For a preliminary injunction to issue "a litigant must show '(1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction were not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.'" *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting *CityFed Financial Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)).

The district court correctly concluded that appellants failed to show a substantial likelihood of success on the merits. When the Hatch-Waxman Act's forfeiture provisions are viewed in the context of the statute's incentive structure, it becomes clear that

Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute. *See Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317–18 (D.C. Cir. 2010). We will thus affirm the district court's decision to deny appellants' motions for a preliminary injunction. *See Apotex, Inc. v. FDA*, 449 F.3d 1249, 1253–54 (D.C. Cir. 2006).

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or petition for rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC., *et al.*

Plaintiffs,

v.

Civil Action
No. 10-517 (RMC)

KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services, *et al.*,

Defendants.

MEMORANDUM OPINION

The question presented is whether the U.S. Food and Drug Administration ("FDA") was arbitrary and capricious when it applied the reasoning of a recent D.C. Circuit opinion, with which the FDA disagrees, to the facts of the instant dispute when time is of the essence and the Solicitor General has not yet decided whether to move for rehearing.

Plaintiffs in this consolidated case, Apotex, Inc. ("Apotex"), and Roxane Laboratories, Inc. ("Roxane"), are two manufacturers of generic drugs. They assert that it is the height of arbitrariness for the FDA to explain its own reading of the "clear" language of the statute and then apply the contrary reasoning of the Circuit, with the effect of allowing a third generic

drug manufacturer to get 180 days of marketing exclusivity starting, perhaps, as early as April 6, 2010. The Court disagrees. On this record and with these facts, the FDA recognized that it is bound to follow the Circuit opinion until and unless it gets that opinion modified or reversed. The parties' recourse is to the Circuit.

I. BACKGROUND

A quick summary of a lot of litigation should suffice to present the current controversy. Readers are directed to the Circuit's decision, *Teva Pharms. USA, Inc. v. Sebelius*, 595 F. 3d 1303 (D.C. Cir. 2010), for details.

Teva Pharmaceuticals USA, Inc., is a generic drug manufacturer. It filed an abbreviated new drug application ("ANDA") with the FDA and claimed that its generic versions of Cozaar and Hyzaar (losartan) did not infringe the '075 patent held by Merck, the brand name drug manufacturer. Because Teva's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), if the FDA approved the ANDA, Teva would have 180 days of marketing exclusivity for its generic drugs immediately upon expiration of Merck's last related patent. *See id.* § 355(j)(5)(B)(iv)(I). Instead of suing Teva for patent infringement, Merck responded by "delisting" the patent with the FDA. *See id.* § 355(j)(5)(D)(i)(I)(bb)(CC). As interpreted by the FDA, the Food, Drug, and Cosmetic Act, as amended (codified in relevant part at 21 U.S.C. § 355), provides for forfeiture of exclusivity if the first ANDA filer (here, Teva) fails to market its product within a

specified time after patent delisting. *See Teva Pharms. USA, Inc., v. Sebelius*, 638 F. Supp. 2d 42, 48 (D.D.C. 2009), *rev'd and remanded by* 595 F. 3d 1303 (D.C. Cir. 2010). It is undisputed that Teva did not go to market within that time period after Merck delisted the '075 patent, since the FDA had not approved Teva's ANDA and FDA did not publicize that Merck had withdrawn the patent from FDA's list. The FDA determined that Teva had thus forfeited its right to exclusivity and this Court agreed. *See generally id.*

The Circuit did not. Holding that the structure of the Act does not permit the unilateral action of a patent holder to deprive a first ANDA applicant of its short-term marketing exclusivity, the Circuit reversed and directed this Court to give relief to Teva. *Teva*, 595 F.3d at 1319 ("We therefore reverse the judgment of the district court, but, as the court has yet to address the appropriateness of each form of relief that Teva has sought, we remand for further proceedings....").

On remand, the FDA informed the Court that it had learned that the Merck '075 patent had actually expired prior the filing of Teva's lawsuit, due to Merck's failure to pay maintenance fees to the U.S. Patent and Trademark Office after it "delisted" the patent. FDA argued that patent expiration is another and separate basis on which, under the Act, it might be found that Teva had forfeited marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(VI). FDA advised the Court that it had posted a notice at www.regulations.gov in Docket No. FDA-2010-N-0134, and was receiving comments on how it should

interpret § 355(j)(5)(D)(i)(VI), under which exclusivity may be forfeited if a patent expires. FDA promised to make its determination no later than March 26, 2010. FDA urged the Court to withhold its remedy order for Teva until after FDA decided the question of statutory interpretation. However, because Teva had persuaded the Circuit to expedite its appeal and the mandate, in light of the anticipated expiration of the last Merck patent on April 6, 2010 (except for Merck's failure to maintain the patent), this Court issued its order on relief on March 16, 2010. *See* Dkt. # 28. On the FDA's motion to amend the order, the Court issued its final order on March 26, 2010. *See* Dkt. # 33.

On March 26, 2010, as predicted, FDA issued a letter to ANDA applicants and notified them that, while it disagreed with the Circuit opinion, it had applied the Circuit's reasoning to answer "no" to the question of whether a brand name drug manufacturer could unilaterally cause its patent to expire and, thus, force a forfeiture of a first ANDA applicant's right to marketing exclusivity for 180 days. *See* Dkt. # 34. Therefore, the FDA announced, it would not prevent the first ANDA applicant, Teva, from enjoying its 180-day marketing exclusivity for its generic losartan drugs, and would not approve any other ANDA application during that time period. *Id.* The consolidated petitions for a preliminary injunction immediately followed in an attempt to prevent FDA's approval of Teva's ANDA.

Apotex and Roxane are both generic drug manufacturers who compete with Teva. Each Plaintiff has a pending ANDA for generic versions of

Cozaar and Hyzaar and each has been preparing to begin marketing after April 6, 2010. Apotex participated as *amicus curiae* in the Teva suit; it was granted intervenor status on remand. Apotex filed the instant complaint on March 30, 2010, along with a proposed very short briefing schedule, with which the FDA agreed. Teva filed a motion to intervene on the same day. The Court adopted the briefing schedule and granted Teva intervenor status. Roxane filed its separate suit on March 30; it agreed to the same briefing schedule and moved, without opposition, to consolidate the cases. The Court granted both motions. This abbreviated opinion recognizes the parties' need for a quick decision.

II. LEGAL STANDARDS

There are four familiar factors that govern whether preliminary injunctive relief should be awarded and they are analyzed on a sliding scale. In other words, the stronger the case on one point, the lesser the evidence needs to be on another. In order to obtain a preliminary injunction, a party must demonstrate that: (1) it has a likelihood of success on the merits; (2) it will suffer irreparable injury in the absence of preliminary relief; (3) other interested parties will not be substantially injured if the requested relief is granted; and (4) granting such relief would serve the public interest. *See Katz v. Georgetown Univ.*, 246 F.3d 685, 687-88 (D.C. Cir. 2001); *Biovail Corp. v. FDA*, 448 F. Supp. 2d 154, 155 (D.D.C. 2006). The likelihood of success requirement is the most important of these factors. *Id.* "Without any probability of prevailing on the merits, the Plaintiffs' purported injuries, no matter how

compelling, do not justify preliminary injunctive relief." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999). "[A] party seeking a preliminary injunction must demonstrate...'a likelihood of success on the merits,'" not merely the existence of "questions 'so serious, substantial, difficult and doubtful, as to make them fair ground for litigation.'" *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008).

Review of final agency action is conducted under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* FDA's March 26, 2010 letter to ANDA applicants for generic versions of Cozaar and Hyzaar (losartan) drug products constituted final agency action as it relates to Plaintiffs and is, therefore, subject to court review. The FDA does not argue otherwise. Under the APA, a court will uphold agency action unless it is arbitrary or capricious or inconsistent with the law. *See* 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001).

III. ANALYSIS

The Court cannot find that the FDA was arbitrary or capricious when it politely expressed its disagreement with a D.C. Circuit decision that had ruled against the agency, but nonetheless applied the reasoning of the Circuit to a different but, on these facts, closely related question. Given the facts and law in this record, the Court finds that Plaintiffs have a very slim chance of success on the merits. This factor does not support issuance of a preliminary injunction.

The irreparable harm predicted by Plaintiffs is not to be ignored. Their drug products would be precluded from competing with Teva's for 180 days and, according to Plaintiffs, that head start would have a multi-million dollar consequence that could not be recovered. FDA points out that "[m]ere injuries, however substantial, in terms of money, time and energy necessarily expended," do not constitute irreparable harm. *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). "[F]inancial harm alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business," *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001), a standard neither Plaintiff meets. Plaintiffs also argue, however, that consumers will suffer from significantly higher prices if Teva's generics do not have immediate generic competition. This latter argument is forestalled by the Circuit's finding that the structure of the Act indicates a clear pro-consumer congressional intent to reward a first ANDA applicant that challenges a brand manufacturer's patent with short-term marketing exclusivity, as a matter of law and public policy. This factor counsels against an injunction.

As to harm to others, an injunction as sought by Plaintiffs would certainly injure Teva and would prevent public access to any generic of these drugs. This factor does not support issuance of an injunction.

The fourth factor to consider is the public interest. Plaintiffs argue that consumers are entitled to brisk competition among generic drug manufacturers so

that they will enjoy lower prices. The argument is contrary to the teaching of *Teva*, where the Circuit described the structure of the statute as pro-consumer because the first ANDA filer is encouraged by the reward of exclusivity to hurry generic drugs to market. *Teva*, 595 F.3d at 1318 ("The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device....The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick their necks out....").

Thus, this factor also fails to support preliminary injunctive relief.

IV. CONCLUSION

The Court will deny Plaintiffs' motions for a preliminary injunction [Dkt. # 4 in No. 10-517; Dkt. # 4 in No. 10-521]. The Court agrees that FDA properly followed the logic of the D.C. Circuit's decision in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303. A memorializing order accompanies this memorandum opinion.

Date: April 2, 2010

/s/
ROSEMARY M. COLLYER
United States District Judge

APPENDIX C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

[March 26, 2010]

SENT VIA TELEFAX

Docket No. FDA-20l0-N-0134

Dear ANDA Applicants:

This letter addresses whether the March 4, 2009 expiration of U.S. Patent No. 5,608,075 ('075 patent) affects the first applicant's eligibility for l80-day exclusivity for generic versions of Merck's Cozaar and Hyzaar drug products, and supplements the March 11, 2010 letter to ANDA applicants that was posted at www.regulations.gov in Docket No. FDA-20l0-N-0134. As explained below, in light of the Court of Appeals' decision in *Teva Pharms., USA, Inc. v. Sebelius*, No. 09-5281 (D.C. Cir. Mar. 2, 2010) ("*Teva* slip op."), we have concluded that the expiration of the '075 patent does not result in a forfeiture of the first applicant's eligibility for exclusivity for ANDAs referencing Cozaar and Hyzaar.

Background

FDA has pending before it ANDAs referencing Cozaar (losartan potassium) Tablets and Hyzaar (losartan potassium and hydrochlorothiazide)

Tablets. Among the patents submitted to FDA for Cozaar and Hyzaar, and thus relevant to the approval date for these ANDAs, is the '075 patent. FDA's Orange Book shows that the '075 patent was submitted by Merck, and that Merck later requested delisting of the patent. Merck has also recently informed FDA that the expiration date for the '075 patent should be revised from March 4, 2014, to March 4, 2009.[1] The Orange Book currently displays the March 4, 2009 expiration date for the '075 patent.

The timing of approval of ANDAs referencing Cozaar and Hyzaar will be affected by, among other things, any 180-day exclusivity under section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the Act) available to a first applicant to challenge the '075 patent.[2] Under the Act, as amended by the MMA, a 180-day exclusivity period will not delay approval of any ANDA referencing Cozaar or Hyzaar if the exclusivity has been forfeited by the first applicant. See section 505(j)(5)(D)(i). The

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[1] Apotex notified FDA on March 9, 2010, that records of the U.S. Patent and Trademark Office (PTO) showed that the '075 patent had expired no later than March 30, 2009, due to non-payment of fees. Pursuant to the procedure described in 21 C.F.R. § 314.53(f), FDA sought information from Merck regarding the correct expiration date for the '075 patent. By letters of March 12, 2010, Merck stated that the correct expiration date for the '075 patent is March 4, 2009.

[2] The 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar is governed by section 505(j)(5)(B)(iv) and related provisions, as modified by the Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the MMA).

delisting of the '075 patent by Merck and the March 4, 2009 patent expiration date implicate two distinct 180-day exclusivity forfeiture provisions in the Act, sections 505(j)(5)(D)(i)(I) and (VI), respectively.

Delisting of the '075 Patent

The U.S. Court of Appeals for the D.C. Circuit recently considered the effect of the delisting of the '075 patent on a first applicant's claim to 180-day exclusivity arising from a paragraph IV certification to that patent. *Teva* slip op. The court reviewed the delisting provision, section 505(j)(5)(D)(i)(I)(bb)(CC). The Agency had applied this provision in previous adjudications such that delisting of the patent for any reason by the NDA holder could result in forfeiture. Teva had asserted that FDA's interpretation of the delisting provision, although applied by FDA only in adjudications involving other drugs and different parties, was both subject to immediate review by the court and not supported by the statute.[3] The court, in a 2-1 decision, agreed with Teva on both grounds, and ruled that Merck's delisting of the '075 patent could not be the basis for forfeiture of exclusivity by the first applicant for generic Cozaar and Hyzaar. Slip op. at 29.

The D.C. Circuit, in response to a request from Teva, issued the mandate on an expedited basis on

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[3] On July 31, 2009, the U.S. District Court for the District of Columbia found that it had jurisdiction to review the matter, but granted judgment in favor of the government on the merits. *Teva Pharms. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42 (D.D.C. 2009).

March 12, 2010, and remanded the case to the district court.[4] On March 26, 2010, the district court amended an order it had issued on March 16, 2010, to clarify that Teva has not forfeited its 180-day exclusivity under the Failure to Market provision, section 505(j)(5)(D)(i)(I). The district court stated that forfeiture due to patent expiration under section 505(j)(5)(D)(i)(VI) was not raised in Teva's Complaint and was not addressed by the D.C. Circuit in either its March 2, 2010 Opinion or in the March 12, 2010 issuance of the mandate. The district court ordered FDA to file a notice of its decision on the '075 patent expiration issue by 5 p.m. on March 26, 2010.

Expiration of the '075 Patent

When Teva first raised the question of 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar before the district court in June 2009, FDA's records showed a March 4, 2014 expiration date for the '075 patent, and no outside party had brought any other expiration date for the patent to the Agency's attention. It was only after the March 2, 2010 *Teva* decision that FDA was notified by Apotex that the Patent and Trademark Office records showed that the '075 patent had expired for failure to pay fees. Now that Merck has confirmed to FDA that the '075 patent expired on March 4, 2009, FDA is addressing whether the patent expiration is a separate basis, apart from the delisting, for forfeiture

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[4] The Solicitor General is considering seeking rehearing of the Court of Appeals' decision. If rehearing is sought by the government and granted, the mandate would be recalled.

of exclusivity.[5] To obtain comment from interested parties on the effect of the revised patent expiration date, FDA sent a letter to ANDA applicants on March 11, 2010, and opened a public docket for submission of comments (FDA-2010-N-0134).

FDA has considered these submissions, as well as the relevant statutory provisions, regulations, and case law, in developing the views described in this response.[6]

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[5] In *Teva*, the government argued that the court should not address the dispute concerning 180-day exclusivity being pressed by plaintiff Teva until FDA had decided that issue. One basis for the government's position was the potential that factual and/or legal issues specific to the circumstances associated with the Teva claim would require an FDA analysis that would, at a minimum, be useful to the court in its decision-making. The court rejected that position. FDA believes that the new and complicated issues raised by the expiration of the patent at issue in this case provide a good example of why courts should await an agency decision in a particular matter rather than anticipate an agency's decision based on previous rulings in similar matters.

[6] Due to the limited amount of time remaining before April 6, 2010, when one or more ANDAs referencing Cozaar and Hyzaar are expected to be eligible for final approval, FDA initiated its request for comment on the effect of a March 4, 2009 expiration date for the '075 patent before it had received the confirmation from Merck of the correct expiration date. Further, because of the exceptional circumstances of this case, FDA is making a decision on 180-day exclusivity before April 6, 2010. Because of the possibility that relevant facts will change, it is FDA's usual practice to wait until at least one ANDA is otherwise eligible for final approval before the Agency makes decisions regarding 180-day exclusivity. Among other considerations underlying FDA's decision to address the patent expiration at this time is the *Teva*

Neither the district court nor the D.C. Circuit addressed the effect of the expiration of the '075 patent on the first applicant's eligibility for 180-day exclusivity, nor could they have done so because, as noted, when the courts ruled, neither they nor FDA was aware of the fact that the '075 patent had expired. Therefore, FDA is addressing the matter here. First, the Agency analyzes the issue as if it were writing on a clean slate, and interpreting and applying the statute without reference to the recent *Teva* decision. Second, the Agency describes the effect of the Court of Appeals' reasoning in the *Teva* delisting decision on the outcome in this particular patent expiration matter.

Merck, the NDA holder, has notified FDA that the sole patent giving rise to a claim of 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar, the '075 patent, has expired. The patent information provided to FDA by the NDA holder controls for patent certification purposes. *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("FDA operates in a purely ministerial role, relying on NDA holders to provide the Agency with accurate patent information."). Therefore, in assessing the first applicant's claim to exclusivity, FDA will rely on Merck's statement that the '075 patent has expired.

The effect of a patent expiration on exclusivity is specifically addressed in the 180-day exclusivity

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court's decision on 180-day exclusivity based on events involving the same patent at issue in the current matter.

provisions applicable to the ANDAs referencing Cozaar and Hyzaar. Section 505(j)(5)(B)(iv) of the Act, as amended by the MMA, states:

> Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

"Subparagraph (D)" describes how a first applicant will forfeit its 180-day exclusivity period upon the occurrence of different types of a "forfeiture event" with respect to that applicant. Section 505(j)(5)(D). Among the defined events resulting in forfeiture is "Expiration of All Patents," which occurs when "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired." Section 505(j)(5)(D)(i)(VI). If this forfeiture event applies to a first applicant, the applicant forfeits exclusivity immediately upon the expiration of all patents as to which it qualified as a first applicant.[7] If there is only

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[7] The forfeiture events described in sections 505(j)(5)(D)(i)(II)-(V) are similarly immediate in effect if they are found to apply to a first applicant. It is interesting to note the contrast between these "immediate" forfeiture events, which provide no

one patent that serves as a basis for 180-day exclusivity, when that patent expires, there will be no exclusivity for the drug product, and the Agency may approve any otherwise approvable ANDA.

Under FDA's longstanding interpretation, once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished. This is true

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opportunity for the first applicant to use its exclusivity period once the forfeiture event has occurred, and the "Failure to Market" forfeiture event described in 505(j)(5)(D)(i)(I), which provides that upon the occurrence of certain events, rather than face immediate forfeiture, the first applicant will have the opportunity to begin commercial marketing of the drug product and thus start the running of its 180-day exclusivity period. For each of the events set out in 505(j)(5)(D)(i)(I)(bb), the first applicant has 75 days from the date of the specified event to begin marketing and receive the benefits of exclusivity. These provisions describe events that could occur with respect to "the first applicant *or any other applicant*" (emphasis added), as well as the patent deli sting provision interpreted by the court in *Teva*. Presumably, Congress structured this exclusivity forfeiture provision so that, even if it is an applicant other than a first applicant that triggers a forfeiture by, for example, obtaining a final decision of non-infringement, the first applicant will nevertheless have a limited opportunity to benefit from being the first to challenge the patent. It is reasonable for FDA to conclude that, once at least one applicant has obtained a final court decision or settlement stating that the patent at issue is invalid or not infringed–or the patent has been delisted by the NDA holder because it does not meet the patent listing requirements–Congress sought to balance the benefits derived from the exclusivity incentive against the delay in the availability of generic drugs resulting from that exclusivity, and thus established a limit on the length of time during which the exclusivity would be available. In the case of patent expiration, Congress concluded that not even a limited 180-day exclusivity barrier to approval was warranted once the patent expired.

under both the pre-MMA 180-day exclusivity provisions and the MMA exclusivity provisions applicable to the ANDAs referencing Cozaar and Hyzaar. The pre-MMA exclusivity provisions did not explicitly address whether 180-day exclusivity could survive the expiration of the patent. In addressing that statutory gap, FDA stated that once a patent expires, the correct certification to the patent is a "paragraph II" certification pursuant to section 505(j)(2)(A)(vii)(II)("that such patent has expired"). Once the application no longer contains a paragraph IV certification to the patent, the applicant no longer has a basis to obtain exclusivity as to that patent. This was held to be a reasonable interpretation of the pre-MMA exclusivity provision. *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 356-57 (D.N.J. 2003). Moreover, even when the D.C. Circuit found in *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), that the pre-MMA exclusivity provisions would not permit an NDA holder's delisting of a patent to defeat a first applicant's claim on exclusivity, the court noted that "as Ranbaxy and Teva acknowledged at oral argument, the text and the structure of the [pre-MMA] statute suggest a distinction between expiration and delisting such that the first generic applicant may no longer retain exclusivity when the patent has expired." *Id.* at 126 n.3 (citing, inter alia, *Dr. Reddy's Labs.*). The forfeiture provision at section 505(j)(5)(D)(i)(VI), enacted in the MMA, thus embodies the familiar principle that 180-day exclusivity does not survive patent expiration.[8]

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[8] The MMA did not revise the descriptions of patent

The issue presented by the expiration of the '075 patent is not whether, as a general rule, exclusivity will be forfeited pursuant to section 505(j)(5)(D)(i)(VI) upon the expiration of a patent, but whether a patent expiration for failure to pay fees is an exception to this rule.[9] The Agency's view is that, if it were writing on a clean slate, it would interpret the statute so that patent expiration for any reason is a patent expiration forfeiture event. FDA believes that interpretation is most consistent with the plain meaning of the words of the statute and with a workable and appropriate approach to administration of the statute.

The text of the patent expiration forfeiture event provision does not provide a basis to distinguish between "natural patent expiry" and expiration for some other reason.[10] Section 505(j)(5)(D)(i)(VI) refers broadly to forfeiture when "all of the patents...have expired." There is no language qualifying the type of expiration the Agency is to consider relevant for

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certifications set forth at section 505(j)(2)(A)(vii).

[9] Teva, for example. appears to acknowledge that forfeiture will occur upon "natural patent expiry." March 18, 2010 Comment from Teva at 3.

[10] Teva's comment does not define "natural patent expiry." For example, that term presumably could encompass both the expiration of the original 17 or 20 year term of a patent and the expiration of the term of certain patent claims that have been extended under 35 U.S.C. § 156. FDA's requirements do not limit the type of patent expiration information that may be submitted to FDA. 21 C.F.R. § 314.53.

forfeiture.[11] Thus, there is no apparent statutory basis for the Agency to conclude that only some patent expirations result in forfeiture.

Some of the comments noted a number of reasons why FDA should create an exception to patent expiration forfeiture when the patent expires because the patent owner has failed to pay applicable fees. Among these are concerns about the lack of certainty regarding the expiration when the patent expires due to non-payment of fees. The March 18, 2010 comments from Teva and from Olsson, Frank & Weeda (OFW) identify situations in which a patent that has expired can be "revived" through payment by the patent owner of fees. Teva comment at 2-3; OFW comment at 3-4, 9-10.

Although it may well be the case that a patent that has expired for failure to pay fees could, in certain circumstances, be revived, this possibility alone is an inadequate basis to maintain that a later expiration date must control. As an initial matter, FDA will not change the applicable patent expiration date unless the NDA holder tells the Agency to do so. If the NDA holder (who is also likely to be the patent owner or licensee) notifies FDA that the patent has expired due to failure to pay fees, it can be presumed

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[11] Based on the lengthy list of patents that expired on March 4, 2009, that was submitted as Attachment B to the March 9, 2010 Apotex letter raising the '075 patent expiration issue, expiration for failure to pay fees is not uncommon. Nonetheless, FDA is not aware of any other case in which it has been notified by an NDA holder that a patent that had been submitted to FDA and listed in the Orange Book has expired due to non-payment of fees.

to have resolved at least to a reasonable certainty the finality of the patent expiration. Further, the concerns about uncertainty of expiration would presumably extend to all situations in which a patent has expired due to failure to pay fees, including those in which, although 180-day exclusivity is not an issue, reliance on a later expiration date could delay generic drug approvals. For example, if an NDA holder notified FDA that a patent on a drug as to which no ANDA had yet been submitted had expired due to failure to pay fees, but FDA refused to accept the NDA holder's representation because of uncertainty that the patent would remain "expired," future ANDA applicants would be required to submit patent certifications for a patent that may have its natural patent expiration years in the future. If the NDA holder is sufficiently certain its patent has expired that it notifies FDA of that fact, FDA believes that generic drug applicants are entitled to rely on that patent expiration date in seeking approval for their drug products.

Finally, in assessing what expiration date should control for purposes of 180-day exclusivity, it is appropriate for FDA to continue to rely on the NDA holder's representations to FDA. *Teva v. Leavitt*, 548 F.3d at 106. In this case, for example, although Apotex brought the question of the correct expiration date for the '075 patent to FDA's attention, the Agency did not consider the patent expiration date to be March 4, 2009 (and publish that date in the Orange Book) until Merck notified FDA that March 4, 2009 was the correct date. Had Merck maintained that the patent expiration date remained March 4,

2014, FDA would have retained the March 4, 2014 date in its records and relied on that date for patent certification, exclusivity, and application approval purposes. As stated in FDA's regulations,

> Unless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list [the Orange Book]. If the new drug application holder does not change the patent information submitted to FDA, ... an abbreviated new drug application under section 505(j) of the act submitted for a drug that is claimed by a patent for which information has been submitted must, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.

21 C.F.R. § 314.53(f). Even though information on patent expirations due to failure to pay fees is available from the PTO, it would not be an appropriate use of FDA resources for FDA to forgo its ministerial role in these matters and make its own assessments of patent expiration. In light of the commenters' concerns about the uncertain nature of these patent expirations, it would seem particularly important that the Agency continue to defer to the NDA holder's judgment regarding the expiration of its patent.

The expiration of a patent is a specific basis for forfeiture of exclusivity under the MMA, and it also necessitates a change in the ANDA applicants' patent certifications. The MMA patent certification provisions, like the pre-MMA provisions, state that the appropriate certification to an expired patent is a "paragraph II" (that such patent has expired). Section 505(j)(2)(A)(vii)(II). Upon expiration of a patent, a paragraph IV certification to the patent automatically becomes invalid. *Ranbaxy Labs Ltd. v. FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished). Thus, a paragraph IV certification to the expired '075 patent is invalid, and the appropriate certification to the patent is "paragraph II." The 180-day exclusivity provision at section 505(j)(5)(B)(iv) directs that FDA determine whether an ANDA "contains a [paragraph IV] certification ... and is for a drug for which a first applicant has submitted an application containing such a certification." When a first applicant's ANDA does not contain a valid paragraph IV certification or a non-first applicant's ANDA no longer contains a paragraph IV certification, the 180-day exclusivity provision at section 505(j)(5)(B)(iv), by its own terms, does not apply.[12] Thus, permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute.

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[12] The MMA also defines a "first applicant" eligible for exclusivity as an applicant that, among other things "submits a substantially complete application that contains *and lawfully maintains* [a paragraph IV certification]." Section 505(j)(5)(B)(iv)(II)(bb) (emphasis added). An applicant cannot lawfully maintain a paragraph IV certification to a patent that has expired.

For the reasons described above, FDA concludes that if it were assessing this issue without reference to the *Teva* decision, it would find that, under the plain language of the statute, because the '075 patent will have expired by the time any ANDA referencing Cozaar or Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity. Moreover, even if the statutory language is considered ambiguous, FDA concludes loss of exclusivity under these circumstances is most consistent with the statute's text and goals, and provides the most reasonable way of administering the statute.

Effect of *Teva* Decision on Patent Expiration Forfeiture

FDA does not believe it can assess the effect of expiration of the '075 patent due to nonpayment of fees on exclusivity for generic Cozaar and Hyzaar without consideration of the D.C. Circuit's *Teva* decision and the reasoning in that decision regarding the delisting of the '075 patent.

In *Teva*, the D.C. Circuit concluded that Teva is entitled to exclusivity, in spite of the fact that the NDA holder has requested delisting of the patent, based on the "structure" of the statute, regardless of the words of the statute.[13] Moreover, the court

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[13] The D.C. Circuit specifically stated:

> We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able

concluded that this analysis was appropriately considered under "*Chevron* step one," *i.e.*, that there was no statutory ambiguity that FDA is free to resolve based on its understanding of the statute and the industry it regulates. Slip op. at 29. After rejecting Teva's "linguistic" argument, slip op. at 24, the court adopted a "structural argument" based on the pre-MMA *Ranbaxy* case. Slip op. at 24. It found that the structure of the MMA exclusivity provisions, as with the pre-MMA exclusivity provision considered in *Ranbaxy*, does not permit an NDA holder to "unilaterally" deprive the generic applicant of its exclusivity on the basis of delisting.[14] Slip op. at 5, 29.

> to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva's ANDAs for losartan products, fails at Chevron step one.

Slip op. at 29.

[14] The *Teva* court's decision suggests that it believed the statute would permit innovator companies to delist patents at will to deprive the first applicant of exclusivity, i.e., that "Brand manufacturers are ... free to delist challenged patents whenever they please ...." Slip op. at 24, 25. Patent listing is not optional. In fact, NDA holders are required by statute to provide patent information to FDA if, but only if, the patent claims the drug product or an approved use of the product, and if "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Section 505(b)(1). Thus, the patent holder may not simply withdraw or change patent information previously submitted to FDA because of some desire to interfere with the 180-day exclusivity of a potential generic competitor. It is, of course, true that FDA does not have the patent expertise to

This reasoning thus appears to preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder. Because the '075 patent expired due to Merck's failure to pay applicable fees, that expiration, consistent with the Court of Appeals' reasoning in *Teva*, is not a grounds for forfeiture of the first applicant's exclusivity. Although FDA believes this result is inconsistent with the plain language of the statute, as discussed above, lit believes it is appropriate to apply the Court of Appeals' reasoning to the present facts. In the event the D.C. Circuit reconsiders and revises the decision in *Teva*, FDA reserves the right to revisit these conclusions regarding 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar.

FDA thus finds that, consistent with the reasoning of the Court of Appeals, despite having been delisted by the patent owner and having expired, the '075 patent nevertheless must be considered to remain a basis for 180-day exclusivity.

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enforce the statutory requirement that appropriate patents be listed or delisted. Because the continued listing of an inappropriate patent, with the resulting blocking of competition, can place the NDA holder in jeopardy of antitrust damages, considerations of antitrust liability may well be factors in innovator decisions to withdraw patent information previously submitted. In fact, settlement of disputes between innovator companies and the Federal Trade Commission can result in patent delistings. *See, e.g.*, Report, *In the Matter of Bristol-Myers Squibb Co.*, Docket No. C-4076 (Federal Trade Comm'n, June 20, 2003) (describing delisting of patents for Serzone, Buspar, and Taxol) The *Teva* decision could affect the availability and effectiveness of delisting as a remedy.

FDA will not approve any other ANDA referencing Cozaar or Hyzaar until the first applicant has received approval of its ANDA, begun commercial marketing, and the 180-day exclusivity period has expired.[15] The Agency makes this finding even though it is not the result that FDA, as the agency that administers the statute, believes is appropriate given the relevant statutory language or the policies underlying the statute.

Conclusion

For the reasons described above, the Agency has concluded that, in light of the D.C. Circuit's decision in *Teva*, the March 4, 2009 expiration of the '075 patent for failure to pay applicable fees does not result in forfeiture of the first applicant's 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar. If you have any questions regarding this decision, please contact Dave Read, Regulatory Counsel, Office of Generic Drugs at (240) 276-9310.

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[15] We note that even though the *Teva* litigation has proceeded on the assumption that a first applicant will receive approval and begin marketing promptly after all applicable patent and exclusivity barriers expire, the rule derived from this case would presumably apply even if the first applicant did not promptly obtain approval and begin to market, *e.g.*, because of changes in the application that required additional review, unsatisfactory inspections, or unavailability of materials. In such cases, FDA could be barred from approving otherwise approvable subsequent ANDAs until either the first applicant eventually triggered its exclusivity with commercial marketing and the 180-day period expired, or the delisted patent expired "naturally," with the result that competition from lower priced generic drugs would be delayed.

Sincerely,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

[March 26, 2010]

APPENDIX D

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued Dec. 7, 2009 Decided March 2, 2010
No. 09-5281

TEVA PHARMACEUTICALS USA, INC.,
APPELLANT
v.
KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH & HUMAN SERVICES, ET AL.,
APPELLEES

Consolidated with 09-5308

Appeals from the United States District Court for the District of Columbia,
(No. 1:09-cv-01111-RMC)

Michael D. Shumsky argued the cause for appellant. With him on the briefs were *Jay P. Lefkowitz* and *Gregory L. Skidmore*.

Carmen M. Shepard and *Kate C. Beardsley* were on the briefs for cross-appellant Apotex, Inc. in No. 09-5308.

Drake Cutini, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Eugene M. Thirolf Jr.*, Director, David S. Cade, Acting General Counsel, United States Food

and Drug Administration, *Michael M. Landa,* Acting Associate General Counsel, and *Eric M. Blumberg,* Deputy Chief Counsel.

Carmen M. Shepard and *Kate C. Beardsley* were on the brief for *amicus curiae* Apotex, Inc. in support of appellees.

Before: HENDERSON and GRIFFITH, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* WILLIAMS.

Dissenting opinion filed by *Circuit Judge* HENDERSON.

WILLIAMS, *Senior Circuit Judge*: This is the latest installment in a long-running series of cases concerning an incentive that Congress established for companies to bring "generic" versions of branded drugs to market faster than they otherwise might. Teva Pharmaceuticals USA, Inc., a manufacturer of generics, has received tentative approval from the U.S. Food and Drug Administration to sell losartan potassium products—used primarily to treat hypertension. The approval will become final once the "pediatric exclusivity period"[1] ends, following the expiration of the last remaining patent on Merck's pioneered versions of the same drugs, sold under the names Cozaar and Hyzaar. When that date arrives

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[1] This is a six-month extension of the time during which all generic competition against a branded drug is prohibited, see 21 U.S.C. § 355a; it is not a subject of dispute here.

(April 6, 2010), Teva believes that it should be entitled to the six-month period of marketing exclusivity that generic drug makers earn, in some circumstances, for successfully taking the risks and bearing the costs of showing the invalidity or inefficacy of a patent that a brand-name drug maker has said blocks competing products. See *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998) (describing the incentive regime established by the Hatch-Waxman Act of 1984); *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120, 121-22 (D.C. Cir. 2006).

Thwarting its receipt of that entitlement, however, is an FDA interpretation of the operative statutory regime (the Food, Drug, and Cosmetic Act, as amended by various other laws, codified in relevant part at 21 U.S.C. § 355) that will allow not only Teva but all generic manufacturers to sell their approved losartan potassium products right out of the gate. In short, Teva says that, effective April 6, 2010, the agency's interpretation will deprive the company of the competitive advantage Congress has said it should enjoy.

To ward off this danger, Teva filed suit in the federal district court for the District of Columbia in June 2009, seeking a declaration that the relevant FDA policy is unlawful and an injunction compelling the agency to act in accordance with Teva's reading of the statute. Despite protestations by the government that the matter was not ripe for review and that Teva lacked standing, the district court reached the merits of the claim—but ruled in the FDA's favor. *Teva*

Pharmaceuticals U.S.A, Inc. v. Sebelius, 638 F.Supp.2d 42 (D.D.C. 2009). Teva now appeals that decision. We agree that the suit is justiciable, and hold that the FDA's interpretation is inconsistent with, and thus foreclosed by, the statutory scheme.

* * *

In the process of obtaining FDA approval to sell a pioneering new drug, an applicant lists publicly all of the patents that, it believes, would be infringed by "bioequivalent" versions of the product sold by other companies. *Ranbaxy*, 469 F.3d at 121-22 (discussing 21 U.S.C. § 355(a)-(b)(1)). Prospective generic competitors need not, however, take these lists as gospel. After a new drug hits the market, they can effectively challenge the brand maker's pronouncement by filing a certification that a proposed generic version of the brand drug would not run afoul of one (or more) of the putatively blocking patents, either because the patent is invalid or because the generic maker has found a way to design around it. See *id.* at 122 (discussing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). The generic producer's filing, called a "paragraph IV certification" in our past cases, comes in the course of the generic's own application for FDA approval, known as an Abbreviated New Drug Application, or ANDA. See *id.* (discussing 21 U.S.C. § 355(j)(2)).

Filing a paragraph IV certification comes with a risk, though: it constitutes an act of patent infringement, 35 U.S.C. § 271(e)(2)(A), with the hazard of sparking costly litigation. In order, then, to "compensate [generic] manufacturers for research

and development costs as well as the risk of litigation from patent holders," *Teva Pharmaceuticals USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008), the statute provides that the first company to file an ANDA containing a paragraph IV certification earns an "exclusivity" period of 180 days, during which the FDA may not approve for sale any competing generic version of the drug at issue, *id.* (discussing 21 U.S.C. § 355(j)(5)(B)(iv)). This promise of initial marketing exclusivity is thus intended to increase competition by expediting the availability of generic equivalents. See *id.*; *Serono Laboratories, Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

A potential bug in the system is the ability of the brand manufacturer, after a generic has filed a paragraph IV certification, to announce that in fact the challenged patent is not one that protects the drug at issue and to ask the FDA to "delist" the patent, thus purporting to pull the rug from under the paragraph IV certification. In *Ranbaxy* we considered "whether the FDA may delist a patent upon the request of the [brand manufacturer] after a generic manufacturer has filed an ANDA containing a paragraph IV certification so that the effect of delisting is to deprive the applicant of a period of marketing exclusivity." 469 F.3d at 125. The answer, we said, was no; an FDA policy that allowed brand manufacturers to strategically delist challenged patents, thereby unilaterally stripping generic manufacturers of marketing exclusivity, was "inconsistent with the structure of the statute." *Id.*

Ranbaxy, however, interpreted the law as it stood before Congress amended it in 2003 via the Medicare Prescription Drug, Improvement, and Modernization Act, Pub.L. No. 108-173, 117 Stat. 2066. *Id.* at 122 n. *. Three times since the effective date of the amendments, the same series of events at issue in *Ranbaxy* has arisen—once involving the generic manufacturer Cobalt Pharmaceuticals and the brand drug Precose, made by Bayer; once involving the generic manufacturer Hi-Tech Pharmacal Co. and the brand drug COSOPT, made by Merck; and now involving Teva, the drugs Cozaar and Hyzaar, and Merck. In the first two instances, the generic makers presented arguments to the FDA why they should still, in the modified statutory regime, be entitled to exclusivity notwithstanding the brand companies' delisting a challenged patent. Teva itself responded to the FDA's solicitation of comments in the Cobalt matter, advocating the same pro-exclusivity reading of the amended statute's treatment of post-paragraph-IV-filing delisting requests. See Letter from Marc Goshko, Executive Director, Teva North America, In Response to FDA Request for Comments re Generic Drug Applications for Acarbose Tablets (Oct. 16, 2007), in Joint Appendix ("J.A.") 78 et seq. In both cases, the FDA ruled that the 2003 amendments required a different outcome from the one *Ranbaxy* ordered under the old version of the law.

The agency pointed to the 2003 amendments' addition of a critical new term to the statute: the "forfeiture event." See 21 U.S.C. § 355(j)(5)(D)(ii). On the occurrence of any one of six defined scenarios, the

law now says, the entitlement to a 180-day exclusivity period "shall be forfeited by a first applicant." See *id.* In both the Cobalt and Hi-Tech disputes, the FDA decided that the facts at issue, paralleling those in *Ranbaxy* and our case, had satisfied the terms of the first listed forfeiture event, "failure to market," and in each case denied the generic manufacturer exclusivity.

The statutory definition of the first listed forfeiture event is as follows:

> (I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—
>
> (aa) the earlier of the date that is—
>
> (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
>
> (BB) 30 months after the date of submission of the application of the first applicant; or
>
> (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least

1 of the following has occurred:

> (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
>
> (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.
>
> (CC) *The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.*

21 U.S.C. § 355(j)(5)(D)(i)(I) (emphasis added).

The FDA stated its view of the matter in terms echoing the so-called "first prong" of *Chevron, U.S.A. Inc. v. NRDC*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984), see, e.g., *Mova*, 140 F.3d at 1067, explaining: "The effect of patent delisting on eligibility for 180-day exclusivity is expressly

addressed by the [preceding] plain language." Dorzolamide Hydrochloride-Timolo Maleate Ophthalmic Solution-180-day generic drug exclusivity, Dear ANDA Applicant Letter (Oct. 28, 2008) ("Hi-Tech Letter") at 14 n. 15., J.A. 121 n. 15. A company otherwise entitled to exclusivity always forfeits it, said the agency, if events occur satisfying both paragraphs (aa) and (bb). *Id.* Paragraph (aa) gets checked off, thanks to its subsection (BB), as soon as 30 months have passed since the generic maker filed its ANDA—which had long since happened in both Cobalt's and Hi-Tech's cases. And paragraph (bb) is taken care of 75 days after the brand manufacturer delists the challenged patent (under subsection (CC)), regardless of the purpose or circumstance of the delisting request. *Id.* In the later of the two letter rulings, the FDA wrote that it had "considered and rejected in both this case and in the matter described in the [Cobalt] Decision, the argument that eligibility for 180-day exclusivity following the [brand maker's] voluntary withdrawal of its patent should be governed not by the [new] forfeiture provisions, but by the rule established in *Ranbaxy*." Hi-Tech Letter at 14, J.A. 121. Even though neither Cobalt nor Hi-Tech could have sold its generic drug before the date that the FDA said amounted to a "failure to market" event (since unchallenged patents protected the relevant brand drugs until a good deal later), the agency announced that both companies had forfeited exclusivity. Both Cobalt and Hi-Tech sought judicial review, were denied relief in district court, and didn't appeal.

Teva filed the ANDAs at issue in this case on December 18, 2003, for Cozaar, and May 24, 2004, for Hyzaar. Both contained a paragraph IV certification targeting Merck's U.S. patent No. 5,608,075, which does not expire until 2014, and left unchallenged Merck's other, earlier-expiring patents on the drugs. In response to Teva's filing, Merck chose not to sue for infringement, as it might have. Instead, on March 18, 2005, Merck asked the FDA to delist the 075 patent, which the agency did, though without making the action public until April 18, 2008. Appellees' Br. at 17. As of the present date, the FDA has awarded tentative approval to Teva's ANDAs, see *Teva,* 638 F.Supp.2d at 58 n. 12, and also to an ANDA filed by a competitor of Teva's, Apotex Inc., to sell generic Hyzaar, see Reply Br. at 11 n. 9. Though the FDA does not formally announce which ANDA filer was the first to submit a paragraph IV certification with respect to a brand drug (or whether any generic manufacturer is officially entitled to exclusivity) until the date on which generic sales can actually begin, see 21 C.F.R. § 314.430(b), Teva has every reason to believe that it was the first filer for both drugs at issue here: it points to the fact that the FDA's own website lists the first paragraph IV certification against Hyzaar (i.e., "Losartan Potassium and Hydrochlorothiazide") as having been filed on the very day that Teva filed its own Hyzaar ANDA. See http:// www. fda. gov (enter "Hyzaar ANDA" in search box; select sole result, "[PDF] Paragraph IV Patent Certifications"; scroll to page 16) (last visited December 21, 2009).

But in light of the Hi-Tech Letter, Teva saw the writing on the wall: under the interpretation of the "plain language" of the amended statute that the FDA had twice adopted, Teva had by the fall of 2008 *already* forfeited the exclusivity it believed it had earned—on August 12, 2006 for the generic Cozaar ANDA, and on January 16, 2007 for the generic Hyzaar ANDA.[2] Moreover, the agency had twice rejected the contention, made once by Teva itself as a commenter, that its chosen interpretation of the statute was untenable for a number of reasons, among them that it was inconsistent with *Ranbaxy*. Eschewing presentation of the same argument to the agency for yet a third time, though the first time with its own ANDA directly on the line, Teva went straight to the district court, hoping for a declaratory judgment rejecting the FDA's interpretation and an order that the FDA grant it exclusivity on the date that generic losartan potassium competition would begin, April 6, 2010.

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[2] The calculation under the FDA's understanding of the statute looks like this: With respect to Cozaar, the date satisfying paragraph (aa) of the "Failure to Market" forfeiture event is August 12, 2006 (30 months since the filing of the ANDA, see subsection (BB))—and the date satisfying paragraph (bb) is 75 days after March 18, 2005 (when Merck asked that the drug be delisted, see subsection (CC)); of the two dates, August 12, 2006 is the later one, hence (under the opening clause of § 355(j)(5)(D)(i)(I)) the forfeiture event. With respect to Hyzaar, the analysis is the same, except that 30 months from the date of the ANDA's filing fell on January 16, 2007. See also Hi-Tech Letter at 15 (saying that the subsection (CC) event is calculated from the date of the brand maker's delisting request, not the date that FDA makes public the delisting).

* * *

The posture of this case raises several significant questions about its justiciability. One concerns conventional ripeness. A second, an issue of standing, implicates a potential—though ultimately illusory—conflict between, on one hand, decisions of this court regarding a plaintiff's ability to obtain pre-enforcement review of a policy adopted by an agency in an adjudication and, on the other hand, the well-established teaching of *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992), that the imminent threat of injury inflicted by the defendant and redressable by the court suffices for constitutional standing.

Ripeness

Pre-enforcement judicial review of an agency's policy is available only if the dispute is ripe. *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003). The ripeness inquiry probes the fitness for review of the legal issue presented, along with (in at least some cases) "the hardship to the parties of withholding court consideration." *Id.* at 808, 123 S.Ct. 2026. The "fitness" prong of the analysis generally addresses "whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *National Ass'n of Home Builders v. U.S. Army Corps of Engineers*, 440 F.3d 459, 463 (D.C. Cir. 2006).

In this case, the substantive issues Teva raises are undoubtedly "purely legal" in the relevant sense. They turn on questions of statutory construction, see *Shays v. FEC*, 414 F.3d 76, 95 (D.C. Cir. 2005), and the interpretations chosen by the FDA and proposed by Teva both constitute bright-line rules, impervious, so far as appears, to factual variation. This in itself largely answers the question whether delay might afford additional "concrete[ness]"; it would not. As to finality, that largely resolves into the questions whether the FDA actually has a policy, whether it's clear what will happen when the FDA applies the policy to Teva, and whether in any event it's sufficiently likely that the policy will matter at all, given possible uncertainty whether Teva would be entitled to exclusivity even if the agency's take on 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (CC) matched Teva's.

While the FDA could in principle change its position as to the effect on generics' exclusivity of brand makers' requests to delist, an about-face seems extraordinarily unlikely. In its brief, the agency maintains, as it did in the Cobalt matter and the Hi-Tech matter, that the interpretation it adopted in those instances is *compelled* by the statute and that arguments to the contrary are plainly futile. Appellees' Br. at 42-43 ("[T]he plain language of subsection (CC) makes clear that the provision applies *whenever* a patent is withdrawn by the [patent holder.]" (emphasis in original)). The mere theoretical possibility that an agency could alter its views on a legal issue before enforcing them against a party has not, in the past, precluded pre-enforcement review of those views. The same possibility exists for

rulemakings, as we observed in *Association of Bituminous Contractors, Inc. v. Andrus*, 581 F.2d 853, 859 (D.C. Cir. 1978), and for less finely chiseled agency decisions, see *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000). As in *Appalachian Power,* there is here virtually no doubt, as a practical matter, what approach the agency will apply to Teva. And the implication of the FDA's position for any exclusivity that Teva would otherwise merit is equally clear: as discussed above, the unambiguous result of the agency's interpretation is that any such entitlement is already forfeited.

The government argues, however—relying chiefly on *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999)—that the issue nevertheless remains unfit for review because the agency's challenged interpretation may not be dispositive of the question whether Teva ultimately deserves exclusivity. In *Pfizer* a brand manufacturer (Pfizer) filed suit alleging that the FDA's mere acceptance of an ANDA for processing was unlawful because the proposed generic drug differed in a crucial respect from the product it sought to replicate. 182 F.3d at 978. We found the suit unripe, suggesting that despite the FDA's tentative approval of the generic's ANDA, grounds for uncertainty over whether the generic drug would ever be approved for sale persisted, posing concerns for "piecemeal litigation": we instanced a possible FDA finding of a lack of bioequivalence, a matter that we obviously assumed the tentative approval left open. *Id.* at 980.

The absence of any colorable factual dispute in Teva's case compels a different outcome from *Pfizer*. The FDA makes no suggestion that any possible deficiency or uncertainty in Teva's ANDA could thwart final approval. It offers no reason to doubt the conclusion that the first paragraph IV certification against Hyzaar, filed on May 24, 2004, was the paragraph IV certification against Hyzaar that Teva filed on May 24, 2004—which in turn dictates that Teva has satisfied the threshold requirement for exclusivity. The agency does caution that one or more of the statutory "forfeiture events" other than a "failure to market" might in any case deprive Teva of exclusivity before final approval–but as Teva's counsel ably demonstrated at oral argument, any such outcome is virtually inconceivable: Teva will not withdraw its ANDA, see 21 U.S.C. § 355(j)(5)(D)(i)(II); it will not amend its paragraph IV certification, see § (D)(i)(III); it has already obtained tentative approval, see § (D)(i)(IV); there is no indication that it will enter a collusive agreement with Merck, see § (D)(i)(V); and the now-delisted patent will not expire, see § (D)(i)(VI). See Oral Argument Tr. at 29-30 (Dec. 7, 2009). In short, the question before us is one of pure statutory interpretation; we know precisely what the FDA thinks the answer is; and its resolution will almost certainly determine whether Teva is entitled to the exclusivity it claims.

The second prong of the ripeness analysis addresses "whether *postponing* judicial review would impose an undue burden on" the parties. *National Ass'n of Home Builders*, 440 F.3d at 464 (emphasis in

original). This court has frequently suggested that hardship is not a *sine qua non* of ripeness. See *id.* at 465 ("[W]here ... there are no significant agency or judicial interests militating in favor of delay, [lack of] hardship cannot tip the balance against judicial review." (second bracketed alteration in original, internal quotation marks omitted)); *Electric Power Supply Ass'n v. FERC*, 391 F.3d 1255, 1263 (D.C. Cir. 2004) ("The hardship prong under the ripeness doctrine is largely irrelevant in cases ... in which neither the agency nor the court have [*sic*] a significant interest in postponing review."); *AT & T Corp. v. FCC*, 349 F.3d 692, 700 (D.C. Cir. 2003) ("The 'hardship' prong of the *Abbott Laboratories* [*v. Gardner*, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)] test is not an independent requirement divorced from the consideration of the institutional interests of the court and agency. Thus, where there are no institutional interests favoring postponement of review, a petitioner need not satisfy the hardship prong." (internal citation omitted)); *Village of Bensenville v. FAA*, 376 F.3d 1114, 1120 (D.C. Cir. 2004) ("[A]lthough the FAA reasonably asserts that the municipalities will not 'suffer [any] immediate hardship from an EIS,' Respondent's Br. at 23, we see no benefit to us in *postponing* review[.]" (emphasis and second bracketed alteration in original)). In this case we need not consider the effect of a failure to show hardship, as Teva faces at least one harm from delayed judicial review cognizable in the ripeness analysis: a near-certain loss of the first-mover advantage to which the company claims entitlement.[3]

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[3] Teva also alleges hardship resulting from the severe impact of

If Teva is right on the merits (as we must assume it is for purposes of the ripeness inquiry, see *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1014 (D.C. Cir. 2002)), then as of April 6, 2010, it will be entitled to start enjoying its exclusivity period and to continue doing so for 180 days before additional firms lawfully enter the market. This "first-mover advantage" is a valuable asset. In *Mova* we observed "the loss of [a generic's] officially sanctioned head start" can, at least in some circumstances, yield a "severe economic impact." 140 F.3d at 1066 n. 6 (internal quotation marks omitted). If we refrained from adjudicating this dispute now, Teva would almost certainly face competition from Apotex on April 6, see 21 C.F.R.

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uncertainty on investment decisions that it must make well before the first legal opportunity to sell its generic, whether as an exclusive (as it claims) or not (under the FDA's view). Delayed resolution of the issues in this case will, depending on the assumptions under which it operates, either (1) cost the company much of a valuable (and lawful) commercial opportunity, if it mistakenly assumes that the FDA view will prevail and therefore refrains from investing sufficient resources to prepare for the increased demand that would accompany an exclusive as opposed to a non-exclusive product launch, or (2) waste hundreds of millions in company resources invested in anticipation of fully exploiting its exclusivity, if it mistakenly assumes that its view will prevail. See Declaration of David Marshall, Vice President of New Products Portfolio Strategy for Teva Pharmaceuticals USA, Inc., at 4-8, J.A. 128-32. (Of course a straddling investment decision would entail some of each cost.) We express no view as to whether such harm counts in the ripeness analysis. Cf. *Exxon Mobil Corp. v. FERC*, 501 F.3d 204, 208 (D.C. Cir. 2007) (hardship ample where postponing review would cause uncertainty and cost to *prospective* applicant for approval to build pipeline and would "tend to inhibit or delay investment" in a project Congress had deemed important).

§ 314.105(d) (explaining that a "tentative" approval is the same as a final approval with a delayed effective date)—an injury that would not be remedied by Teva's securing 180 days of exclusivity later on.

District courts in this circuit routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue. See, e.g., *Teva*, 548 F.3d 103 (earliest possible date of generic competition June 29, 2008, see Appellee's Br. at 5; district court decision April 11, 2008, *id.* at 4); *Ranbaxy*, 469 F.3d 120 (earliest possible date of generic competition June 23, 2006, see Appellants' Br. at 11; district court decision April 30, 2006, *id.* at 1). This makes good sense; the exclusivity reward that Congress made available as an incentive for patent challenges is time-sensitive, and where there is no material ambiguity about essential facts a court can readily decide whether it has been earned in advance of generic competition's onset. The alternative approach—delaying review until the agency has made its technically tentative decisions final—puts a court in an awkward bind, unless it miraculously manages to resolve the merits issue more or less instantaneously. Apart from that risky and improbable course, there would be two possible stopgaps available to preserve the first-mover advantage. The court could delay *all* generic competition, thereby thwarting the statutory purpose of achieving swift competition by generics (a factor that would in turn weigh against preliminary injunctive relief under the "public interest" component of the standard test). Or it could delay the

entrance of the exclusivity claimant's generic rivals into the market, thereby giving the claimant precisely the relief it seeks, simply in order to allow the court time to decide whether such relief was warranted. The technical possibility that a judge might embrace one of these highly imperfect alternatives can hardly be thought to protect Teva from the hardship made likely by delayed review.

When the question at issue is well-defined, and when withholding judicial consideration would cause undeniable harm, as here, ripeness concerns pose no obstacle to pre-enforcement review.

Standing

The FDA embraced the statutory interpretation that Teva now seeks to challenge not in a rulemaking but in two adjudications to which Teva was not a party (though actively commenting in one). Our past cases suggest some uncertainty whether a dispute in that posture can ever be justiciable. See, e.g., *Radiofone, Inc. v. FCC*, 759 F.2d 936, 938 (D.C. Cir. 1985) (opinion of then-Judge Scalia) ("All persons adversely affected by [a] rule ["addressed, so to speak, to the world at large"] would have standing to challenge its compliance with legal prescriptions designed for their protection....The situation is different, however, when an interpretation of a statute, or some other legal principle, is set forth *as the rationale of an adjudication*." (emphasis in original)).

But straightforward application of hornbook doctrine yields the conclusion that Teva has standing.

Article III of the Constitution requires that a federal court plaintiff allege an actual or imminent injury that is fairly traceable to the defendant's challenged conduct and redressable in the judicial proceeding. *Lujan*, 504 U.S. at 560-61, 112 S.Ct. 2130. In this instance, the latter two elements are clearly satisfied. Any imminent deprivation of Teva's allegedly deserved exclusivity would be directly attributable to the FDA's statutory interpretation. And if we agreed with Teva on the merits, we (or the district court) could issue precisely the declaration it has sought, announcing that requests to delist challenged patents should have no more legal significance in the amended statutory regime than they did in the old one, as per *Ranbaxy*, 469 F.3d at 126.

The "injury" prong of the standard standing inquiry is a bit thornier—but only to the extent of the trivial uncertainty whether the FDA will on April 6, 2010 stick to the interpretation that Teva attacks here. As discussed in the ripeness analysis above, however, we find no uncertainty to speak of on the matter. It is clear what the FDA will do absent judicial intervention and what the effect of the agency's action will be. The inescapable implication is that Teva faces an imminent threat of the same harm that has sufficed for Article-III injury purposes in all of our past drug-approval cases: the impending prospect of allegedly unlawful competition in the relevant market. See, e.g., *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1497 (D.C. Cir. 1996) ("[W]here...a statutory provision reflects a legislative purpose to protect a competitive interest, the protected competitor has standing to require

compliance with that provision."); *Ranbaxy*, 469 F.3d 120 (adjudicating a dispute in which the only injury at issue was the prospective loss of a generic manufacturer's 180-day period of marketing exclusivity). For the purpose of the classic constitutional standing analysis, it makes no difference to the "injury" inquiry whether the agency adopted the policy at issue in an adjudication, a rulemaking, a guidance document, or indeed by ouija board; provided the projected sequence of events is sufficiently certain, the prospective *injury* flows from what the agency is going to do, not how it decided to do it. Cf. *City of Los Angeles v. Lyons*, 461 U.S. 95, 106 n. 7, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983) ("[T]o have a case or controversy ... [plaintiff] would have to credibly allege that he faced a realistic threat from the future application of the City's policy.").

The question, then, is whether the normal application of the constitutional standing doctrine is suspended when the court's knowledge that an agency is about to inflict injury on a party derives from an agency policy that originated in an adjudication (or several). The strongest support for such a principle would be *Sea-Land Service, Inc. v. Department of Transportation*, 137 F.3d 640, 648 (D.C. Cir. 1998), in which we rejected a pre-enforcement challenge to an agency interpretation born of an adjudication, noting that a policy's "mere precedential effect within an agency is not, alone, enough to create Article III standing, no matter how foreseeable the future litigation" involving the plaintiff. We have articulated a similar idea, albeit in weaker form, on numerous other occasions. See, e.g.,

Shipbuilders Council of America v. United States, 868 F.2d 452, 456 (D.C. Cir. 1989) ("[W]e know of no authority recognizing that the mere potential precedential effect of an agency action affords a bystander to that action a basis for complaint."); *American Family Life Assurance Co. v. FCC*, 129 F.3d 625, 629 (D.C. Cir. 1997) ("*AFLAC*") ("[W]e have said before, and we say again, that the 'mere precedential effect of [an] agency's rationale in later adjudications' is not an injury sufficient to confer standing on someone seeking judicial review of the agency's ruling." (quoting *Radiofone*, 759 F.2d at 939)).

In all of these cases, we rebuffed efforts to obtain pre-enforcement review of policies embraced by agencies in adjudications. In each instance, however, the failure to demonstrate standing is more naturally understood as arising from the lack of a sufficiently imminent and concrete injury than from some sort of ad hoc exception to otherwise-universally applicable constitutional doctrine. *Radiofone*, for example, addressed whether parties allegedly aggrieved by reasoning employed by the FCC in an adjudication could appeal the agency's order even though the recipient of the order had since ceased doing business. 759 F.2d at 937-38. There was no suggestion in any of the panel's three opinions—including then-Judge Scalia's, which didn't in any case garner a majority for its standing passage—that the parties seeking review were at risk of injury from imminent application of the principle the agency had articulated. *Shipbuilders* similarly concerned no identifiable prospective application of the allegedly

offending policy. We explicitly noted, in fact, that plaintiffs had failed to present "specific, concrete facts demonstrating that the challenged [ruling would] harm" them, adding that their "hypothesizing ... never descends from a highly general plane; it remains at a considerable distance from the more concrete pleas" needed to establish standing. *Shipbuilders*, 868 F.2d at 457. While the opinion also framed the complaint as an impermissible "request for judicial advice—a declaration that a line of agency rulings should henceforth have no precedential effect," *id.* at 456, we simply did not address the scenario in which a line of agency rulings threatened a party with an imminent injury otherwise ample for Article III purposes.

Sea-Land, too, did not involve a party pointing to a particular imminent application of the disputed agency policy. The justiciability problem in that case arose from the "principle that prevailing parties lack standing to appeal," 137 F.3d at 647—which is undoubtedly correct as a general matter, but which does not foreclose review of a case in which a party is aggrieved not by the "mere potential precedential effect of an agency action," *Shipbuilders*, 868 F.2d at 456, but instead by the impending *application* of an agency's statutory interpretation, the firmness of which is not in dispute, on a fast-arriving date certain. The *Sea-Land* opinion, to be sure, phrased the proscription against challenges to agency precedent *qua* precedent as one applying "no matter how foreseeable the future litigation." 137 F.3d at 648. But we could not possibly have purported to overturn well-established Supreme Court precedent

holding that an *imminent* threat of injury suffices for standing, see *Lujan*, 504 U.S. at 560, 112 S.Ct. 2130-particularly in a case not involving the slightest allegation of such a threat. A more sensible reading of *Sea-Land* is one that leaves it consistent with *Lujan* and its equally binding progeny: merely foreseeable future litigation resulting from a statutory interpretation that an agency has adopted in an adjudication is, "alone," 137 F.3d at 648—i.e., without more—too speculative to satisfy Article III's injury-in-fact requirement. An agency's imminent application of its established interpretation of a statute, at the potential cost of hundreds of millions of dollars to the regulated firm, remains, by contrast, as sufficient for standing purposes today as it was before *Sea-Land*. See Marshall Declaration at 4-5, J.A. 128-29 (explaining why Teva "stands to lose hundreds of millions of dollars in net revenues during its first year of generic losartan potassium products sales as a direct result of the [FDA's policy]").

No other case we've decided concerning a pre-enforcement challenge to an agency interpretation adopted via adjudication counsels a contrary result. See *AFLAC*, 129 F.3d at 628 ("Petitioner reports no litigation on the horizon ... no simmering disputes about to erupt into a lawsuit[.]"); *Shell Oil Co. v. FERC*, 47 F.3d 1186, 1202 (D.C. Cir. 1995) ("Shell's allegations of injury rest on a hypothetical scenario.... Although such injury is not inconceivable, we are unpersuaded that it is *imminent*." (emphasis in original)); *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 674 (D.C. Cir. 1994) (finding impact of agency's challenged position on party seeking review

"nebulous and remote"); *Aeronautical Radio, Inc. v. FCC*, 983 F.2d 275, 284 (D.C. Cir. 1993) ("There is no indication in the record ... that the Commission is likely to attempt to [enforce the challenged interpretation against TRW, the party seeking review]. TRW's alleged injury is therefore merely conjectural." (internal quotation marks omitted)).

We have, on the other hand, allowed a party to challenge in advance an agency policy adopted via adjudication when the prospect of impending harm *was* effectively certain. In *International Brotherhood of Electrical Workers v. ICC*, 862 F.2d 330 (D.C. Cir. 1988), a union sought judicial review of the Interstate Commerce Commission's exercise of jurisdiction to review an arbitration award—even though the ICC, having accepted jurisdiction, had ruled *in favor of* the union. 862 F.2d at 334. We found ripeness and standing requirements satisfied, noting that "[b]ecause of the ICC's decision to review arbitration awards, the union will be subject to agency review in future cases involving disputes" of the same type. *Id.* As we later explained, *International Brotherhood* stands for the proposition that the "concrete cost of an additional proceeding is a cognizable Article III injury," *Sea-Land*, 137 F.3d at 648—notwithstanding that the source of the harm was an agency position adopted in an adjudication whose outcome was no longer at issue. Teva's alleged injury threatens to impose no less of a "concrete cost" and with no less certainty.

We have, moreover, explicitly sanctioned review of a case in the present posture—albeit while framing

the justiciability question as one of ripeness rather than standing. *Association of Bituminous Contractors v. Andrus*, 581 F.2d 853, 858-59 (D.C. Cir. 1978), was precisely a pre-enforcement challenge to a policy adopted in a previous adjudication by the Interior Board of Mine Operations Appeals. The doctrine of standing has undoubtedly evolved significantly since the time of that decision (though not generating any new limits on imminent injuries that happen to be traceable to adjudicative rules)—but the case does demonstrate that we have previously considered the lawfulness of an agency policy with precisely the kind of provenance as the policy Teva challenges, where imminent application of the policy was about to inflict injury. See also *Independent Insurance Agents of America, Inc. v. Hawke*, 211 F.3d 638 (D.C. Cir. 2000) (adjudicating dispute over agency interpretation adopted in letter ruling to which district court plaintiff was not party); *Air Transport Ass'n of America, Inc. v. FAA*, 291 F.3d 49 (D.C. Cir. 2002) (same, where dispute concerned letter ruling to which circuit court petitioner was not party).

We see no basis for concluding that this court has created an exception to the Supreme Court's constitutional standing doctrine excising cases like Teva's from the class of otherwise justiciable matters. Teva presents a valid Article III case or controversy.

* * *

On the merits, we review de novo the district court's grant of summary judgment to the FDA. See *Kersey v. Washington Metropolitan Area Transit Authority*, 586 F.3d 13, 16 (D.C. Cir. 2009). We

evaluate the FDA's interpretations of the Food, Drug, and Cosmetic Act adopted in letter rulings under the familiar two-part *Chevron* framework. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004). But see Matthew C. Stephenson and Adrian Vermeule, Chevron *Has Only One Step*, 95 Va. L.Rev. 597 (2009).

Teva offers two principal reasons to conclude that the FDA may not allow a brand manufacturer's request to delist a challenged patent to trigger a statutory "forfeiture event" resulting in the loss of a generic's exclusivity. One reason takes the form of linguistic analysis focused almost entirely on the text of the "failure to market" forfeiture event and a related provision. The 2003 amendments, Teva explains, introduced a new procedure, a counterclaim in the brand manufacturer's patent infringement suit, through which generic companies can *force* brand companies to delist an improperly asserted patent. See 21 U.S.C. § 355(j)(5)(C)(ii)(I).[4] This counterclaim provision is the only portion of the statute that explicitly provides for the delisting of a patent after it has been challenged in an ANDA. In

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[4] The purpose of this procedure, says Teva, is to offer generics a means of combating brand companies' practice of delaying generic competition by listing "sham patents," baiting a generic into filing a paragraph IV certification, and then filing an infringement suit—which typically brings a 30-month stay of generic competition. Appellant's Br. at 42; see 21 U.S.C. § 355(j)(5)(B)(iii) (creating the stay and subjecting it to various limits such as the generic manufacturer's earlier success in the suit); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 236 (4th Cir. 2002) (describing precisely this delay tactic).

the company's view, that singular reference requires the conclusion that the counterclaim provision describes *the only scenario* in which the FDA may delist a challenged patent. Obviously, then, no other kind of delisting could ever serve as an occurrence satisfying the terms of the "failure to market" forfeiture trigger listed at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

The FDA, for its part, responds that "the plain language of the statute contains no limitation on when delisting can occur." Appellees' Br. at 44. Brand manufacturers are thus free to delist challenged patents whenever they please—and any such delisting satisfies subsection (CC) of the "failure to market" forfeiture section. *Id.* at 45-46. In effect, the agency says, the *counterclaim* provision says nothing about its being an exclusive route to delisting, and if Congress meant to confine subsection (CC) delistings to those arising from the counterclaim procedure, it would have been natural for it to place that limitation in (CC).

While Teva's purely linguistic argument shows its understanding of the relevant language to be perfectly plausible, it hardly rules out alternative readings that, absent consideration of statutory structure, also appear plausible. See *Chevron*, 467 U.S. at 844-45, 104 S.Ct. 2778; *INS v. Cardoza Fonseca*, 480 U.S. 421, 443, 107 S.Ct. 1207, 94 L.Ed.2d 434 (1987) (considering "the structure of the Act" at *Chevron* step one). As the FDA notes, there is simply no express preclusion of non-counterclaim delistings, or of such delistings' triggering forfeiture,

in either of the places one might expect to find one, the counterclaim section or (CC).

This brings us to Teva's structural argument. *Ranbaxy*, Teva notes, concerned an FDA policy with a virtually identical effect. See 469 F.3d at 125. This court condemned that rule, partly because it allowed a brand manufacturer,

> by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity. By thus reducing the certainty of receiving a period of marketing exclusivity, the FDA's delisting policy diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent ... in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire. *The FDA may not, however, change the incentive structure adopted by the Congress,* for the agency is bound "not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes."

Id. at 126 (emphasis added, citation omitted). Nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act altered that essential incentive structure, says Teva, so the preceding portion of *Ranbaxy* remains applicable even under the new regime. Indeed, it is true that the 2003 amendments

say nothing specific to undermine our prior understanding of the statute's intended incentive structure.

But the FDA sees a way in which its interpretation of subsection (CC) accomplishes at least some congressional purpose. Without the possibility of a forfeiture of exclusivity resulting from the delisting of a challenged patent, a generic manufacturer that had been awarded exclusivity could delay all generic competition more or less indefinitely, since by statute the agency can't approve competing generics until 180 days after the first paragraph-IV filer has *begun commercial marketing* of its newly approved product. See 21 U.S.C. § 355(j)(5)(B)(iv)(I). Congress enacted the "failure to market" provision, in the agency's view, precisely to avoid such "parking" of exclusivity; allowing a brand maker to trigger forfeiture by delisting a challenged patent positively furthers that legislative aim. Appellees' Br. at 45. Besides, the agency says, "Consumers benefit from lower drug prices immediately without having to wait for one generic company to enjoy 180 days of exclusivity when the patent owner itself takes the position that a patent should not hinder FDA approval of ANDAs." *Id.*

The real issue, then, is whether the FDA is right that the 2003 addition of the "failure to market" forfeiture provision, 21 U.S.C. § 355(j)(5)(D)(i)(I), altered the statute's incentive structure to the point that *Ranbaxy*'s reasoning no longer controls the agency's treatment of a delisting request in the wake of a paragraph-IV filing.

The terms of § 355(j)(5)(D)(i)(I), quoted in full in the opening of this opinion, create five possible dates on which a generic manufacturer otherwise entitled to exclusivity can forfeit it: (1) 75 days after the agency finally approves the relevant ANDA; (2) 30 months after the generic submits the relevant ANDA; (3) 75 days after a court judgment that the challenged patent is invalid or not infringed; (4) 75 days after a suit over the challenged patent is settled favorably to the ANDA filer; and (5) 75 days after the challenged patent is delisted. No forfeiture occurs, however, unless one of dates (1)-(2) *and* one of dates (3)-(5) have come to pass. See *id.*; FDA Letter re 180-day exclusivity, Docket No. 2007N-0389, ANDA 77-165: Granisetron Hydrochloride Injection, 1 mg/mL, at 5, J.A. 68 ("We find that under the plain language of the statute, 180-day exclusivity is not forfeited for failure to market when an event under subpart (aa) has occurred, but ... none of the events in subpart (bb) has occurred."). Setting aside the subsection at issue in this case—listed as (5) above, and codified as (bb)(CC)—the "failure to market" forfeiture provision does not permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter. No forfeiture can take place unless the brand manufacturer brings an infringement suit against the generic and either loses on the merits or enters an unfavorable settlement agreement. The latter necessarily entails some participation by the generic; the former invariably involves significant expense for the brand manufacturer, and affords the victorious generic the opportunity to ask the court to delay entering final judgment until a date that would not

trigger forfeiture prematurely—before the agency grants final approval to the relevant ANDA.

The FDA's view turns the last alternative among events (3)-(5) into a fundamentally different forfeiture trigger: it is satisfied when the patent targeted in a paragraph-IV filing "is withdrawn by the" brand manufacturer, full stop-meaning that Congress has now explicitly provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity. The agency, however, offers *not a single cogent reason* why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, outside the counterclaim scenario identified by Teva.

The argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate delisting requests fails. Precisely the same could have been said of the version of the statute that *Ranbaxy* addressed, and we nevertheless concluded that its structure precluded an FDA rule allowing the agency "to delist a patent upon the request of the [brand manufacturer]" when the delisting would rob the generic maker of earned exclusivity. 469 F.3d at 125.

The agency fares no better in suggesting that allowing the delisting of challenged patents prevents the ANDA filer from "creat[ing] a bottleneck" blocking generic competition by "parking" its exclusivity. Appellees' Br. at 45. As a parking-prevention device, letting brand makers delist challenged patents in order to trigger a forfeiture of

exclusivity would be completely ineffective; given the incentives for the brand manufacturer, it will be used *only* where its impact on Congress's scheme is most destructive. If the generic appears likely to park its exclusivity, the brand maker will simply refrain from delisting altogether, thus enjoying an extended period during which it faces *no* generic competition while the exclusivity-holder bides its time.[5] If the generic appears unlikely to park its exclusivity, the brand maker can delist well before the generic can go to market, thus eviscerating the exclusivity incentive altogether. In other words, the only case in which a unilateral right for brand makers to delist challenged patents actually results in the outcome the FDA touts is when the brand maker deliberately accelerates the onset of generic competition—an utterly implausible scenario. In other cases, the brand maker either does nothing to prevent parking, or prevents parking that was unlikely to have occurred in any event, but with precisely the effect that *Ranbaxy* proscribed. Thus the "parking" concern offers no reason to conclude that the 2003 addition of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity.

Finally, the FDA's sole effort to root its interpretation in the policy underlying Hatch-Waxman—the thought that the interpretation benefits consumers by allowing full generic

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[5] We note, in fact, that many instances of generics' parking their exclusivity have evidently arisen thanks to agreements with the brand maker itself to delay generic competition. See Federal Trade Commission, Authorized Generics: An Interim Report ch. 2, at 1 (2009).

competition without a 180-day delay—betrays a misunderstanding of the exclusivity incentive. The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted. As Congress deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.

We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva's ANDAs for losartan products, fails at *Chevron* step one. Cf. *Ranbaxy*, 469 F.3d at 126; *Cardoza-Fonseca*, 480 U.S. at 443, 107 S.Ct. 1207.

* * *

One matter remains. Teva's prospective generic losartan competitor, Apotex, sought to intervene as a defendant in Teva's suit before the district court. The court denied the intervention on the ground that Apotex lacked standing. *Teva*, 638 F.Supp.2d at 59. Apotex has appealed that ruling, but has also, with the consent of both parties, expressed its substantive views of this case in an amicus brief, which we have considered no less than if Apotex had formally intervened. As Apotex and the FDA are as a practical matter identically positioned on the issues (though from radically different perspectives), we think it prudent to follow the line of precedent in this circuit declining to assess a would-be intervenor's standing when answering the question wouldn't affect the outcome of the case. See *Comcast Corp. v. FCC*, 579 F.3d 1, 6 (D.C. Cir. 2009) ("We need not decide whether [the harm alleged by a prospective intervenor] is too 'conjectural or hypothetical' to support standing ... because 'if one party has standing in an action, a court need not reach the issue of the standing of other parties when it makes no difference to the merits of the case.'" (quoting *Railway Labor Executives Ass'n v. United States*, 987 F.2d 806, 810 (D.C. Cir. 1993))); see also *McConnell v. FEC*, 540 U.S. 93, 233, 124 S.Ct. 619, 157 L.Ed.2d 491 (2003) ("It is clear ... that the Federal Election Commission (FEC) has standing, and therefore we need not address the standing of the intervenor-defendants, whose position here is identical to the FEC's."). We note that courts appear not to have considered whether a party whose attempt to intervene has been pretermitted in this fashion (or a party whose

standing has otherwise been left unresolved) can seek review of the court's decision on the merits, as a successful intervenor could. Perhaps courts have assumed that that issue could reasonably be kicked up the road to the possible appellate body. Finally, we also note that Apotex might move again for intervention in future proceedings before the district court in this case in light of changed circumstances—specifically that Apotex's ANDA has now earned tentative approval from the FDA, effectively removing the obstacle to standing on which the district court relied.

* * *

We therefore reverse the judgment of the district court, but, as the court has yet to address the appropriateness of each form of relief that Teva has sought, we remand for further proceedings not inconsistent with this opinion.

So ordered.

KAREN LECRAFT HENDERSON, *Circuit Judge*, dissenting:

I dissent from the majority opinion because the issue Teva seeks to litigate—its statutory eligibility vel non to exclusively market generic versions of Cozaar and Hyzaar, brand name drugs manufactured by Merck & Co., Inc. (Merck)—will not be ripe unless and until the United States Food and Drug Administration (FDA) issues its final decision either granting or denying Teva's Abbreviated New Drug Application (ANDA). The United States Supreme Court has established a two-pronged test for determining ripeness, requiring that the court analyze: "(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)). This action satisfies neither prong of the ripeness test as is clear from our decision in *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999).

In that case, Pfizer filed a "citizen petition" with the FDA asking that the agency recognize as "a distinct dosage form" a patented "osmotic pump" used as an extended release mechanism for Pfizer's brand drug Procardia XL. *Pfizer*, 182 F.3d at 977. Almost four years later—with the petition still pending—Mylan Pharmaceuticals, Inc. (Mylan) filed an ANDA to market a generic version of Procardia XL, claiming pharmaceutical equivalence notwithstanding Mylan's product used a different release mechanism. After the

FDA accepted Mylan's ANDA for processing but before it decided whether to approve it, Pfizer filed a suit in district court challenging the FDA's acceptance of the ANDA on the ground that the two products were not equivalent because Pfizer's osmotic pump was a unique dosage form and thus distinct from Mylan's mechanism. The district court held that Pfizer's challenge to Mylan's application was not ripe for judicial review but that its unresolved citizen petition was. *Id.* at 978. On appeal, we found neither challenge ripe.

We first rejected Pfizer's argument that "once having decided, based upon the information contained in Mylan's application, that Mylan's drug uses the same dosage form as Procardia XL®, the FDA will not 'alter its views with respect to the necessity of Mylan filing a suitability petition.' " *Id.* at 978. We explained:

> The decision to accept Mylan's ANDA for processing as a pharmaceutical equivalent to Procardia XL® is ... merely the first step in the agency's approval process. The critical fact remains that the FDA may never approve Mylan's application-whether because it decides in the end that the dosage form of Mylan's drug is different from that of Procardia XL® or for some entirely different reason, such as a lack of bioequivalence. Therefore, "depending upon the agency's future actions ... review now may turn out to have been

> unnecessary" and could deprive the agency of the opportunity to apply its expertise and to correct any mistakes it may have made.

Id. (quoting *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 736, 118 S.Ct. 1665, 140 L.Ed.2d 921 (1998)) (first ellipsis added). Teva faces the same hurdle here. We do not know whether the FDA's final decision will approve Teva's ANDA or what the FDA's reasoning will be if, as the majority forecasts, maj. op. at 1308-10, it does not. The FDA may conclude Teva forfeited its eligibility upon Merck's delisting of its patents, as Teva and the majority insist it will, or it may reject Teva's application based on one of the other forfeiture provisions "or for some entirely different reason, such as a lack of bioequivalence." *Pfizer*, 182 F.3d at 978.[1] Because the FDA has not yet issued its decision we are unable to divine its substance. Given this uncertainty and the consequent possibility the court may not need to resolve the delisting/forfeiture issue after the FDA's final decision, Teva's challenge to the FDA's previous decisions in other proceedings is not now fit for review under the first prong of the ripeness test. In short, "[i]t makes no sense for us to anticipate a

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[1] The FDA's "tentative approval" of Teva's ANDA is not, as Teva suggests, Reply Br. at 10-11, the final word on its generic drug's equivalence. See *Pfizer*, 182 F.3d at 980 (although FDA's post-oral argument tentative approval of Mylan's generic made it "more likely that the FDA w[ould] eventually approve Mylan's drug, the agency's tentative approval cause[d] Pfizer no hardship at present or in the near future, nor d[id] it render Pfizer's challenge fit for review").

wrong when none may ever arise." *Cronin v. FAA*, 73 F.3d 1126, 1132 (D.C. Cir. 1996).

Nor does Teva fare better under the test's hardship prong as we applied it in *Pfizer*. There we explained that Pfizer was not able to "point to any imminent hardship arising from the FDA's acceptance of Mylan's ANDA":

> Before Pfizer could suffer its claimed "economic injury from unlawful competition," FDA approval for a pharmaceutical equivalent to Procardia XL® would have to be not only sought but granted. That has not happened. Therefore "no irremediable adverse consequences flow from requiring a later challenge."

Pfizer, 182 F.3d at 979 (quoting *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164, 87 S.Ct. 1520, 18 L.Ed.2d 697 (1967)). For the same reason, Teva too will suffer no *imminent* hardship if review is postponed. *See Fed. Express Corp. v. Mineta*, 373 F.3d 112, 119 (D.C. Cir. 2004) (hardship prong not satisfied because "postponing review ... w[ould] not be a hardship to [petitioners], let alone a hardship that is '*immediate*, direct, and significant.' " (quoting *State Farm Mut. Auto. Ins. Co. v. Dole*, 802 F.2d 474, 480 (D.C. Cir. 1986))) (emphasis added). As in *Pfizer*, the delay will not "foreclose [the appellant's] right ever to get meaningful judicial *review*," 182 F.3d at 979; upon the FDA's issuance of an adverse final order, Teva is free to seek judicial review—forestalling generic

competition and the loss of the "first-mover advantage," maj. op. at 1311, through appropriate and immediate injunctive relief.[2]

For the foregoing reasons, I would find the appeal is unripe and dismiss it for lack of jurisdiction.[3]

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[2] And contrary to my colleagues' lack of confidence in judicial alacrity, maj. op. at 1311, courts make speedy decisions on injunction applications in ANDA cases all the time. See, e.g., *Apotex, Inc. v. FDA*, C.A. No. 06-627, 2006 WL 1030151 (D.D.C. Apr. 19 2006); *Biovail Corp. v. FDA*, C.A. No. 06-1487 (D.D.C. Aug. 25, 2006); *Merck & Co. v. FDA*, 148 F.Supp.2d 27 (D.D.C. June 2001).

[3] In support of ripeness, the majority asserts: "District courts routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." Maj. op. at 1311 (citing *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008); *Ranbaxy Labs., Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)). Leaving aside what effect a court's routine practice may have on an issue's ripeness vel non, I know of no instance where the district court reached the merits of an ANDA before the FDA has issued *any decision* regarding the plaintiff and the issue raised. In the two cases the majority cites, the district court directly reviewed FDA decisions denying relief to the plaintiffs. *See Teva Pharms.*, 548 F.3d at 105 (reviewing denial of citizen petition contesting FDA's delisting of patent certified in its ANDA); *Ranbaxy Labs., Ltd.*, 469 F.3d at 121 (reviewing denial of citizen petition denial). Here, by contrast, the FDA has taken no adverse action whatsoever regarding the effect of delisting on Teva's ANDA—and apparently will not do so unless and until it denies final approval. Had Teva raised the delisting issue before the FDA in the first instance, its status here might be different.

APPENDIX E

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA
PHARMACEUTICALS
USA, INC.,

Plaintiff,

v.

Civil Action
No. 09-1111 (RMC)

KATHLEEN SEBELIUS,
Secretary of Health and
Human Services, *et al.*,

Defendants.

MEMORANDUM OPINION

Teva Pharmaceuticals USA, Inc. ("Teva"), a manufacturer of generic drugs, seeks a preliminary injunction to invalidate a "Delisting Rule" instituted by the Food and Drug Administration ("FDA"). The FDA contends that there is no such "Delisting Rule." Instead, in informal adjudications regarding other drugs, the FDA has held that a name brand manufacturer's withdrawal of a patent as a basis for its drug(s) (*i.e.*, a request that the patent be "delisted") triggers a forfeiture provision excising the generic company's eligibility for a 180-day exclusive marketing period. Teva contends that by way of these decisions the FDA has created a "rule" that is subject

to challenge. The FDA moves to dismiss, arguing that its decisions do not constitute a final rule subject to challenge and that, because there has been no final agency action on Teva's own request for generic drug approval, the matter is not ripe and Teva lacks standing. The Court held oral argument on July 13, 2009, and now decides that the FDA's motion to dismiss will be denied. Further, the preliminary injunction proceedings are combined with trial on the merits and judgment will be granted in favor of the FDA. The FDA's statutory interpretation is not arbitrary or capricious.

I. BACKGROUND FACTS

A. Statutory Scheme

The Drug and Price Competition and Patent Term Restoration Act of 1983 (the "Hatch-Waxman Amendments"),[1] 21 U.S.C. § 355 & 35 U.S.C. §§ 156, 271, & 282, established a streamlined procedure for FDA approval of generic drugs. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). The original applicant for approval of a drug (the "Innovator") must file a New Drug Application ("NDA"), including data from studies showing the drug's safety and effectiveness. *Id.*; *see also* 21 U.S.C. § 355(a) & (b). The Innovator also is required to submit information on any patent that claims the drug or a method of using the drug for which patent infringement could be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1) & (c)(2).

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[1] The Hatch-Waxman Amendments amended the Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et seq.*

The FDA lists such patent information in a publication called the "Approved Drug Products with Therapeutic Evaluations," commonly known as the "Orange Book." *Id.*; 21 C.F.R. § 314.53(e).

Subsequent applicants who want to manufacture generic versions of the Innovator's drug may file an Abbreviated New Drug Application ("ANDA"). *Mova*, 140 F.3d at 1063; 21 U.S.C. § 355(j). The ANDA is not required to include new safety and effectiveness data, but instead may rely on the safety and effectiveness data in the original filing. 21 U.S.C. § 355(j). In this way, the Hatch-Waxman Amendments were intended both to encourage innovative new drugs and to permit the marketing of lower cost generic drugs quickly. *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987).

An ANDA applicant must certify whether the generic drug would infringe any existing patents relied on and listed by the Innovator. The applicant may certify:

> (I) that the required patent has not been filed;
>
> (II) that the patent has expired;
>
> (III) that the patent has not expired, but will expire on a particular date; or
>
> (IV) that the patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii).[2] A paragraph III certification means that the ANDA applicant does not intend to market the drug until after the patent expires; approval of the ANDA may be made effective on the expiration date. *Id.* § 355(j)(5)(B)(ii). A paragraph IV certification contemplates that the ANDA applicant challenges the validity of the patent or claims that the patent would not be infringed by the generic product proposed in the ANDA. An applicant must provide notice of a paragraph IV certification to the Innovator. *Id.* § 355(j)(2)(B). The filing of a paragraph IV certification constitutes an act of infringement under patent law, 35 U.S.C. § 271(e)(2)(A), and the Innovator, as patent holder, has 45 days to bring suit against the ANDA applicant. *Id.* § 355(j)(5)(B)(iii). If the Innovator brings such a suit, the FDA must delay approving the ANDA for 30 months. *Id.* This provision, known as the 30-month stay, gives the Innovator time to assert its patent rights before the generic competitor is permitted to enter the market. *Mova*, 140 F.3d at 1064. If the Innovator does not bring suit within 45 days, the FDA may approve a paragraph IV ANDA, and the approval may be effective immediately despite the unexpired patent, provided that other conditions have been met. *Id.*; 21 C.F.R. § 314.107(f)(2).

Under certain circumstances, the statute provides a 180-day exclusive marketing period vis-a-vis other ANDA applicants to the first applicant who files an ANDA with a paragraph IV certification. 21 U.S.C.

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[2] Paragraph I and II certifications are not relevant to this case.

§ 355(j)(5)(B)(iv). That is, the first patent-challenging generic applicant may be awarded a six-month period during which that applicant is the only company allowed to sell a generic version of the name brand drug. Thus, the statute may reward the first generic manufacturer that exposes itself to the risk of patent litigation. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005); *Mova*, 140 F.3d at 1064.

Congress amended 21 U.S.C. § 355(j) in 2003 to add the exclusivity provisions raised by Teva in this case. *See* 21 U.S.C. § 355(j)(5)(D) (part of the Medicare Modernization Act of 2003) (the "MMA"); *see* The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003).[3] The MMA contains certain "forfeiture provisions" setting forth the conditions under which an ANDA applicant may lose eligibility for the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i) & (ii). The forfeiture provision at issue in this case is the one that provides that a first ANDA filer will forfeit exclusivity if it fails to market the drug by a certain date:

> (I) Failure to Market. The first [ANDA] applicant fails to market the drug by the later of-
>
> (aa) the earlier of the date that is-
>
> (AA) 75 days after the date on which the approval of the application of the first

[3] The parties agree that the MMA applies to the ANDAs filed by Teva, as they were filed after the MMA was enacted.

applicant is made effective under subparagraph (b)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), *the date that is 75 days after the date as of which*, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters final judgment that includes a finding that the patent is invalid or not infringed.

(CC) *The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved*

> *under subsection (b) of this section* [i.e., the Innovator].

Id. § 355(j)(5)(D)(i)(I) (emphasis added to highlight provision at issue here). Forfeiture occurs only when the "later" of the events in (aa) or (bb) occurs.

The FDA has twice applied the subsection (bb)(CC) forfeiture provision in public letter decisions, after providing notice and comment. For example, with regard to an ANDA for the drug acrabose, the FDA applied the failure to market forfeiture provision under (bb)(CC), finding that this subsection requires marketing within 75 days from when the patent information is withdrawn by the Innovator. Compl. Ex. 5, Letter from Gary Buehler, Director, Office of Generic Drugs, at 7-9 (May 7, 2008), FDA Dkt. No. 2007-N-0445 ("Acrabose Decision"). The FDA announced its interpretation of subsection (bb)(CC) in broadly applicable terms-"Therefore, FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply *whenever* a patent is withdrawn (or requested to be 'delisted') by the NDA holder." *Id.* at 8 (emphasis added). Likewise, with regard to an ANDA for generic Cosopt, the FDA again explained its interpretation of subsection (bb)(CC) of the MMA-that this subsection applies "whenever" a patent is withdrawn by the Innovator. Compl. Ex. 9, Letter from Gary Buehler, Director, Office of Generic Drugs, at 14 n.15 (Oct. 28, 2008), FDA Dkt. No. 2008-N-0483 ("Cosopt Decision").[4]

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[4] The FDA has determined that the 75 day period runs from the date that the FDA receives the patent holder's request to remove the patent from the Orange Book, even though this date

B. Facts of This Case

The facts of this case are not in dispute. Merck & Co., Inc. ("Merck") is the name brand manufacturer that holds approved NDA No. 20-386 for losartan potassium ("losartan") tablets (sold under the name "Cozaar") and NDA No. 20-0387 for losartan potassium hydrochlorothiazide ("losartan HCTZ") tablets (sold under the name "Hyzaar"). Cozaar and Hyzaar are primarily used to treat hypertension. During the twelve month period that ended March 31, 2009, pharmacists in the United States filled over fifteen million prescriptions for Cozaar and Hyzaar, dispensing 848 million tablets, which amounts to nearly $1.5 billion in sales. Pl.'s Mot. for Prelim. Inj. [Dkt. # 5], Ex. A, Decl. of David Marshall ("Marshall Decl.") ¶ 4.

Merck provided patent information to the FDA for listing in the Orange Book: (1) U.S. Patent No. 5,138,069 ("the '069 patent"); (2) U.S. Patent No. 5,153,197 ("the '197 patent"); and (3) U.S. Patent No. 5,608,075 ("the '075 patent").[5]

Teva filed an ANDA to market generic losartan on December 18, 2003, and an ANDA for generic losartan HCTZ on May 24, 2004. The ANDAs

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generally does not become public until the FDA publishes the request to delist in the Orange Book. Acrabose Decision at 7 n.13; Cosopt Decision at 7.

[5] Merck also provided information regarding another patent regarding the method of use of Cozaar. This patent is not relevant here because Teva does not seek approval for this method of use.

contained paragraph III certifications to the '069 patent and the '197 patent and a paragraph IV certification to the '075 patent. Teva sent a notice of its paragraph IV certification to Merck, but Merck did not sue Teva for infringement within 45 days. Instead, on March 18, 2005, Merck withdrew its reliance on the '075 patent by requesting that the FDA remove it from the Orange Book. Merck holds an additional six-month pediatric exclusivity on the '069 and '197 patents. *See* 21 U.S.C. § 355a(b) (pediatric exclusivity prevents the FDA from approving generic applications for six months after the patent expires). Thus, the '069 patent expires on August 11, 2009, and Merck's pediatric exclusivity with regard to this patent expires February 11, 2010; the '197 patent expires on October 6, 2009, and Merck's pediatric exclusivity expires April 6, 2010. Accordingly, the FDA is barred from approving any ANDAs until April 6, 2010, the date that Merck's pediatric exclusivity on the '197 patent expires.

Under the FDA's interpretation of the law, the time calculations under the failure-to-market forfeiture provision quoted above are not in dispute. Under that provision, an ANDA first-filer loses its eligibility by failing to market its generic drug by the later of two dates. One of the dates is calculated under subsection (aa)—the earlier of the date that is 75 days after the ANDA approval (there is no such date here, as Teva's ANDA has not been approved) or 30 months after the ANDA was submitted (June 19, 2006 for Teva's generic version of Cozaar and November 25, 2006 for Teva's generic version of Hyzaar). In other words, the "earlier" date under

subsection (aa) is June 19, 2006 for Teva's Cozaar ANDA and November 25, 2006 for Teva's Hyzaar ANDA.

The second date is calculated under subsection (bb). Because Merck did not file suit against Teva, the first two events under subsections (bb)(AA) and (BB) which relate to litigation do not apply. Under subsection (bb)(CC), Merck withdrew the patent information on the '075 patent on January 1, 2009. According to the FDA, because Teva did not market its generic drugs within 75 days after January 1, 2009, Teva forfeited exclusivity.[6] The FDA's Acrabose Decision and Cosopt Decision make it clear that the FDA applies the forfeiture provision set forth in (bb)(CC) this way.

Teva brought this suit asking the Court to set aside the FDA's new "Delisting Rule," as reflected in the FDA's Acrabose and Cosopt Decisions. The FDA moves to dismiss for lack of jurisdiction and failure to state a claim. Teva seeks a preliminary injunction and requests that the Court combine the hearing on the preliminary injunction with trial on the merits. *See* Fed. R. Civ. P. 65(a)(2) (a court may advance the trial on the merits and consolidate it with the hearing on preliminary injunction). The FDA did not object to a combined proceeding. Because the issue presented

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[6] This is so even though Teva was barred from bringing its drugs to market because Merck's pediatric exclusivity with regard to the '069 and '197 patents has not expired Teva's right to exclusivity was based only on the '075 patent; if Teva had challenged the '069 and '197 patents, the withdrawal of the '075 patent would not have effectuated a forfeiture.

here is purely a matter of law, the preliminary injunction motion and trial on the merits are consolidated.

II. LEGAL STANDARDS

The FDA moves to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Teva does not challenge a final agency action and that Teva did not exhaust its administrative remedies. A Rule 12(b)(6) motion challenges the adequacy of a complaint on its face, testing whether a plaintiff has properly stated a claim. A complaint must be sufficient "to give a defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). Although a complaint does not need detailed factual allegations, a plaintiff's obligation to provide the grounds for his entitlement to relief "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* Federal Rule of Civil Procedure 8(a), which requires that a complaint contain a short and plain statement of the claim showing that the pleader is entitled to relief, requires a "showing" and not just a blanket assertion of a right to relief. *Id.* at n. 3. A court must treat the complaint's factual allegations as true, "even if doubtful in fact," *id.* at 1965, and must draw all reasonable inferences in the plaintiff's favor. *Macharia v. United States*, 334 F.3d 61, 64, 67 (D.C. Cir. 2003).

While the FDA does not explicitly move to dismiss for lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1), it impliedly seeks a Rule 12(b)(1) dismissal as well by arguing that Teva's claim is not ripe and that Teva lacks standing. On a motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject matter jurisdiction. *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182-83 (1936); *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999). To determine whether it has jurisdiction, a court may consider materials outside the pleadings. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. ANALYSIS

A. Final Agency Action

The FDA contends that Teva has not stated a claim because Teva does not complain of any final agency action. The FDA will not render any decision regarding Teva's ANDAs until April 2010, and the FDA "intends to make a decision regarding 180-day exclusivity when an ANDA for losartan becomes ready for final approval." Def.'s Mot. to Dismiss [Dkt. # 9] at 18. The FDA reasons that the Acrabose and Cosopt Decisions are FDA decisions regarding whether other ANDAs were eligible for the 180-day exclusivity and do not constitute any decision regarding whether Teva's ANDAs for losartan and losartan HCTZ are eligible for the 180-day marketing exclusivity period. The FDA asserts that what Teva really wants is a determination now regarding

whether it will be entitled to exclusivity if and when the FDA approves its ANDAs in the future. The FDA points out that when another generic manufacturer sought advance approval in *Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008), the court held that the manufacturer was not entitled to advance approval of marketing exclusivity. In that case, a generic manufacturer (Hi-Tech) brought suit against the FDA, seeking a finding by the FDA that Hi-Tech was entitled to the 180-day marketing exclusivity period and seeking an injunction to prevent the FDA from granting final approval to any other generic drug producer while Hi-Tech enjoyed its marketing exclusivity. The court held that the manufacturer was not entitled to review until there was final agency action. 587 F. Supp. 2d at 8. In addition, the court in *Hi-Tech* determined that the FDA was not required to approve Hi-Tech's request for exclusivity by a time certain, and the FDA's failure to act with respect to the issue of exclusivity did not constitute final agency action. *Id.* at 9-10.

Because the FDA misconstrues Teva's claim, this case is not analogous to *Hi-Tech*. Teva does not seek an advance determination on its request for exclusivity as Hi-Tech did. Teva challenges the FDA's interpretation of the MMA as arbitrary, capricious, and an abuse of discretion in violation of section 706 of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. *See* Compl. ¶ 68. The FDA has interpreted the MMA forfeiture provision (bb)(CC) as applying "*whenever*" an Innovator withdraws a patent. See Acrabose Decision at 8. In the Cosopt Decision, the FDA felt bound by its Acrabose Decision

and applied the same statutory construction. Cosopt Decision at 14 n.15. The statutory interpretation was not reliant on any particular factual circumstance presented by those cases; it was entirely based on the language of the statute. The FDA interpreted the MMA to authorize exclusivity-divesting patent delistings effectuated by a name brand manufacturer's voluntary request.

The APA provides a cause of action to a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." 5 U.S.C. § 702. Review under the APA is limited to "final agency action"[7] for which there is no other adequate remedy in a court. *Id.* § 704; *Heckler v. Chaney*, 470 U.S. 821, 828 (1985) (a person adversely affected by final agency action is entitled to judicial review so long as no statute precludes review and the action is not committed to agency discretion by law). "Whether there has been 'agency action' or 'final agency action' within the meaning of the APA are threshold questions; if these requirements are not met, the action is not reviewable." *Fund for Animals, Inc. v. Bureau of Land Mgmt.*, 460 F.3d 13, 18 (D.C. Cir. 2006).

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[7] A final agency action "(1) marks the consummation of the agency's decision making process—it must not be of a merely tentative or interlocutory nature; and (2) the action must be one by which rights or obligations have been determined or from which legal consequences will flow." *Domestic Secs., Inc. v. SEC*, 333 F.3d. 239, 246 (D.C. Cir. 2003) (internal quotation marks omitted.)

An "agency action" is "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof." 5 U.S.C. § 551(13). A "rule" is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4). Thus, the term "final agency action" includes an agency's interpretation of a statute. *UAW v. Brock,* 783 F.2d 237, 248 (D.C. Cir. 1986). "[W]hen a legal challenge focuses on an announcement of a substantive statutory interpretation, courts are emphatically qualified to decide whether an agency has acted outside the bounds of reason." *Id.* at 245. Further, an agency's statement of policy is reviewable whether it is set forth in a formal regulation or is articulated in another context, such as a letter ruling. *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676-77 (D.C. Cir. 1994). An agency may establish binding policy through rulemaking procedures or through adjudications which constitute binding precedent. *Brock*, 783 F.2d at 248.[8] An agency's interpretation of its own governing statute is final agency action fit for judicial review. *Id.* Accordingly, the FDA's interpretation of the MMA in the context of the Acrabose and Cosopt Decisions constitutes a rule of decision made through adjudication, and the FDA's interpretation of the MMA constitutes "final agency action" that is subject to review under APA §§ 702

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[8] The FDA argues that the Acrabose and Cosopt Decisions constituted informal adjudication, not rulemaking. For the purpose of this decision, the distinction makes no difference. Both final rues and final orders are reviewable. 5 U.S.C. §706. Further, binding policy, whether created by rulemaking or adjudication, is reviewable. *Brock*, 783 F.2d at 248.

and 704. Thus, Teva has stated a claim under the APA seeking to set aside the FDA's statutory interpretation as arbitrary and capricious under § 706(2).

B. Exhaustion

The FDA also contends that this case should be dismissed for failure to state a claim due to failure to exhaust administrative remedies. FDA regulations require that, before filing suit in court, a party requesting that the FDA take or refrain from taking an action must first use the citizen petition process set forth in 21 C.F.R. § 10.25. 21 C.F.R. § 10.45(b). Exhaustion required by agency regulation, however, is not jurisdictional. *Ass'n of Flight Attendants-CWA v. Chao*, 493 F.3d 155, 158-59 (D.C. Cir. 2007). Courts have the discretion to decline to require exhaustion where a plaintiff would be irreparably harmed by delay, where the agency lacks the power to grant effective relief, or where exhaustion would be futile. *McCarthy v. Madigan*, 503 U.S. 140, 146-49 (1992). Exhaustion is futile when there is a certainty of an adverse decision, *Randolph-Sheppard Vendors v. Weinberger*, 795 F.2d 90, 105 (D.C. Cir. 1986), or when the agency "has evidenced a strong position on the issue together with an unwillingness to reconsider." *James v. HHS*, 824 F.2d 1132, 1137 (D.C. Cir. 1987).

Teva submitted comments in the docket of the Acrabose Decision in which the precise forfeiture issue it now seeks to litigate was raised. The FDA considered and rejected Teva's argument:

> We have considered and rejected the argument made in [Teva's] comments to FDA's docket that eligibility for 180-day exclusivity following the NDA holder's voluntary withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in *Ranbaxy Labs., Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)....These comments argue that the forfeiture event described in section 505(j)(5)(D)(i)(I)(bb)(CC) of the Act applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act. Section 505(j)(5)(C)(ii) contemplates that, as a result of a counterclaim by the ANDA applicant in patent infringement litigation, a court may issue an order requiring that patent information be corrected or deleted. Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision. We do not find this argument persuasive [and] FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Acrabose Decision at 8. The FDA evidenced its strong position and its unwillingness to reconsider in the Cosopt Decision by stating, "[w]e also have considered and rejected in both this case and in the ... Acrabose Decision, the argument that eligibility for 180-day exclusivity following the NDA holder's voluntary

withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in Ranbaxy." Cosopt Decision at 14. The FDA went on to explain, just as it had in the Acrabose Decision, that it reads subsection (bb)(CC) of the MMA to broadly apply whenever an Innovator withdraws a patent and not only when a patent is withdrawn as a result of counterclaim litigation:

> [A]s noted in the Acrabose Decision at pp. 8-9, we also have considered the argument that the forfeiture event described [in subsection (bb)(CC)] applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act.... Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision.... [T]he scope of the patent delisting forfeiture provision is much broader.... FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Id. at 14 n.15. Teva has exhausted its remedies by participating unsuccessfully in the Acrabose litigation and pursuit of administrative remedies would be futile. In these circumstances, the law does not require further administrative exhaustion.

C. Ripeness

Jurisdiction requires that a claim be ripe for decision. Under the Constitution, federal courts are limited to deciding "actual, ongoing controversies."

Honig v. Doe, 484 U.S. 305, 317 (1988). A claim is not ripe for adjudication if it rests upon "'contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *Texas v. United States*, 523 U.S. 296, 300 (1998) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580-81, 105 S.Ct. 3325, 87 L.Ed.2d 409 (1985)). By requiring that claims be ripe before adjudicating them, courts promote judicial economy, avoid becoming entangled in abstract disputes, and ensure a record adequate to support an informed decision when a case is heard. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967).

To show that a claim is ripe, a plaintiff must demonstrate (1) the fitness of the issues for judicial decision, and (2) the hardship to the parties caused by withholding court consideration. *Nat'l Treasury Employees Union v. Chertoff*, 452 F.3d 839, 854 (D.C. Cir. 2006) (citing *Abbott Labs.*, 387 U.S. at 149). To determine the fitness of an issue for judicial review, a court must look to see "whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002) (quoting *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1204 (D.C. Cir. 1998)). A petition for review that presents a "purely legal question" satisfies the "fitness" prong of the test for ripeness. *Edison Elec. Institute v. EPA*, 996 F.2d 326, 333-34 (D.C. Cir. 1993); *see also CropLife Am. v. EPA*, 329 F.3d 876, 884 (D.C. Cir. 2003) (press release announcing that EPA would not consider third party human studies in regulatory decision-making was a statement of a

blanket agency policy that presented a purely legal question, ripe for review); *IBEW v. ICC*, 862 F.2d 330, 335 (D.C. Cir. 1988) (a matter is fit for review when agency's decision is "crystallized"); *Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 695 (D.C. Cir. 1971) (an issue is fit for judicial resolution where there is no need to identify or refine the facts). The "hardship" prong of the ripeness test requires a court to avoid interfering with an agency's decision unless and until the decision involves "effects felt in a concrete way by the challenging party." *Nat'l Automatic Laundry*, 443 F.2d at 696.

The issue raised by Teva—whether the FDA's interpretation of subsection (bb)(CC) of the MMA is arbitrary and capricious under the APA—is purely a legal question fit for judicial review. It is a challenge to the FDA's interpretation of the statute on its face and not as applied to a particular set of facts. There is no need for further factual development as there is no material fact missing from the record that could alter the FDA's interpretation of the MMA.

Further, the decision affects Teva in a concrete way. To explain how it is affected by the right to exclusive marketing and the loss of that right, Teva submitted the declaration of David Marshall, Teva's Vice President of New Products Portfolio Strategy. Mr. Marshall explains that when a generic manufacturer such as Teva files a paragraph IV certification, it takes on the risk of costly and protracted patent litigation. Marshall Decl. ¶ 10. However, by being the first to take on such risk, Teva

became eligible for the 180-day exclusive marketing period. *Id.* ¶ 11. The exclusivity period provides a strong incentive because it provides a permanent advantage—"that officially sanctioned 'head start' permits first entrants to secure distribution channels and access to customers; enter into long-term sales agreements; increase sales across all of its product lines; and retain greater market share in the long-run." *Id.* Under the FDA's interpretation of the MMA as set forth in the Acrabose and Cosopt Decisions, Teva already has lost its right to the 180-day exclusive marketing period; Teva will sell 50-60% fewer losartan tablets during its first year in the market and will experience a loss of hundreds of millions of dollars in net revenue. *Id.* ¶ 16.

Teva's current day-to-day operations are concretely affected by the FDA's interpretation of forfeiture under the MMA. Teva must obtain materials to begin manufacturing generic losartan products in the immediate future, and it must obtain more materials if it is preparing for exclusive marketing than if it is preparing for non-exclusive marketing. *Id.* ¶ 22. If it enjoyed an exclusive product launch, Teva would need to place an order immediately-for delivery no later than August 2009—for the manufacture of the active pharmaceutical ingredient used to make losartan products as well as non-active ingredients and packaging materials. *Id.* ¶ 22-23. Also, Teva would need to dedicate plant capacity and human resources earlier for an exclusive

product launch as opposed to a non-exclusive launch. *Id.* ¶ 24.[9]

The FDA argues that this case is not ripe for review, relying on *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999). In that case, Pfizer sought to prevent the FDA from approving the ANDA of a competitor, Mylan. Pfizer claimed that its drug product had a unique release mechanism and that the FDA could not approve an ANDA without the same release mechanism because ANDAs are required by statute to have the same "dosage form" as the name brand drug. *See* 21 U.S.C. § 355(j)(2)(A)(i)-(iii). Prior to filing suit, Pfizer had filed a citizen petition. The FDA had denied the petition, finding that another release mechanism could provide the same dosage form. 182 F.3d at 978. Pfizer filed suit in district court, and the court granted summary judgment to the FDA. *Id.* Pfizer then appealed, and the D.C. Circuit held that Pfizer did not present a ripe claim. While the FDA had "refused to affirm the negative proposition that no other extended release mechanism could ever be deemed under the statute to

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[9] Mr. Marshall further explains, "Commercial uncertainty will impose an array of irreparable harms on Teva." Marshall Decl. ¶ 25. If Teva manufactures losartan products assuming that it does not have exclusivity and later it is awarded exclusivity, it will not have manufactured sufficient quantity of products to meet the market demand, resulting in reduced sales and loss of customer good will. *Id.* ¶ 26. If Teva manufactures generic losartan products assuming that it has exclusivity and then in April 2010 the FDA decides that it is not entitled to such exclusivity, Teva will have wasted resources manufacturing tons of tablets it cannot and may never sell, forcing Teva to dispose of excess product or liquidate it at a loss. *Id.* ¶ 27.

constitute the same dosage form as Pfizer's," the FDA had not yet applied this finding to any particular set of facts. *Id.* at 979. The court held that Pfizer's challenge raised an abstract disagreement over agency policy and was not sufficiently crystallized to constitute an actual case or controversy. *Id.* at 979-80. The FDA's reliance on Pfizer stems from its mischaracterization of Teva's claim. Unlike Pfizer, Teva does not ask the Court to preclude the FDA from approving a competitor's ANDA. Moreover, Pfizer is distinguishable because there the FDA had not yet applied its policy to a particular set of facts. Here, Teva challenges the FDA's interpretation of the MMA on purely legal grounds.

The FDA also relies on *Biovail Corp. v. FDA,* 448 F. Supp. 2d 154 (D.D.C. 2006). There, Biovail sought to require the FDA to rule on its citizen petition before approving any competing ANDA. Biovail alleged in its citizen petition that a competitor's proposed generic drug posed an unreasonable risk of seizures because it was not bioequivalent to the name brand drug. 448 F. Supp. 2d at 161. The court found that the FDA was not required to rule on the citizen petition by any particular date and that the court would not assume that the FDA would approve an unsafe drug if it did not immediately rule on the citizen petition. *Id.* at 162. In contrast, Teva is not asking the FDA to rule on the issue presented by a particular date; the FDA *already* has interpreted subsection (bb)(CC) of the MMA. To resolve this issue, the Court is not required to presume that the FDA will take any particular action in the future.

Teva's challenge to the FDA's statutory interpretation is ripe for review.

D. Standing

The FDA further suggests that Teva's suit should be dismissed for lack of standing. Lack of standing is a defect in subject matter jurisdiction. See *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987). To have Article III standing, a plaintiff must establish: "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). "This triad of injury in fact, causation, and redressability constitutes the core of Article III's case-or-controversy requirement, and the party invoking federal jurisdiction bears the burden of establishing its existence." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998). A court may "intervene in the administration of the laws only when, and to the extent that, a specific 'final agency action' has an actual or immediately threatened effect." *Lujan v. National Wildlife Federation*, 497 U.S. 871, 894 (1990).

The FDA contends that Teva lacks standing, in that it can show no injury because the FDA has not made a decision regarding Teva's ANDAs. Yet as described above, Teva has been injured by the FDA's

statutory interpretation. The FDA's interpretation imminently will cause Teva to lose its right to exclusive marketing, and Teva already has altered its operations due to this imminent loss. Teva's current operations are affected because it has not ordered the additional materials and dedicated the plant capacity and human resources it would need if it were planning to market its generic losartan products in an exclusive market. Marshall Decl. ¶¶ 22-24. The loss of the 180-day exclusive marketing period imminently will cause Teva to lose the ability to: secure distribution channels and access customers, enter into long-term sales agreements, increase sales across all of its product lines, and retain greater market share in the long-run. *Id.* ¶ 11. Also, the loss of exclusivity imminently will cause Teva to sell fewer losartan tablets during its first year in the market, resulting in a loss of hundreds of millions of dollars in net revenue. *Id.* ¶ 16. Teva has demonstrated standing.

E. APA Challenge to the FDA's Interpretation of the MMA

Teva challenges the FDA's interpretation of the MMA forfeiture provision set forth at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). The APA requires a reviewing court to set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a

clear error of judgment." *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation marks omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986). An agency action may be arbitrary or capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). "[T]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." Id. Rather, the agency action under review is "entitled to a presumption of regularity." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), abrogated on other grounds by *Califano v. Sanders*, 430 U.S. 99 (1977).

When reviewing an agency's interpretation of a statute, a court must undertake a two-step analysis as set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). First, a court must determine whether "Congress has directly spoken to

the precise question at issue" and if so the court must "give effect to the unambiguously expressed intent of Congress." 467 U.S. at 842-43. To decide whether Congress has addressed the precise question at issue, a court must analyze the text, purpose, and structure of the statute. *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 124 (D.C. Cir. 2006).

If the statute is silent or ambiguous on the question, the court must proceed to the second step of the Chevron analysis and determine whether the agency's interpretation is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843. When an agency's interpretation of a statute is challenged at step two, its "interpretation need not be the best or most natural one by grammatical or other standards.... Rather [it] need be only reasonable to warrant deference." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). "The court need not conclude that the agency's construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Chevron*, 467 U.S. at 844 n.11. If the agency's statutory construction is permissible, then the court must defer to the agency's interpretation. *Id.*

At *Chevron* step one, this Court must give effect to the clear intent of Congress as reflected in the statute because subsection (bb)(CC) is not ambiguous on its face. Section 355(j)(5)(D)(i)(I) provides that an ANDA filer will forfeit exclusivity if it fails to market the drug by the later of two dates, and under subsection

(bb)(CC), one of those dates is 75 days after "[t]he patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b) [the Innovator]." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

Teva asserts that the statute is ambiguous if read as a whole. First, Teva argues that the MMA governs only the effect of the withdrawal of a patent by an Innovator, but that it does not address the circumstances in which a patent may be delisted. Teva is correct that the statute does not address when an Innovator may withdraw a patent, but what is important is that the statute does not limit the Innovator's right to withdraw patent information. The Court cannot take on the role of the legislature by creating such limitations when they were omitted by Congress.[10]

Second, Teva argues that subsection (bb)(CC) should only apply when a court has ordered the Innovator to withdraw the patent pursuant to a counterclaim suit filed by an ANDA applicant. The MMA includes a "counterclaim provision" that

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[10] Further, it is not that the FDA made an incorrect judgment about whether the '075 patent should be listed or delisted. The FDA does not adjudge the propriety of patent listings. It is not required to determine the correctness of listings in the Orange Book because it lacks expertise in patent law. *Apotex v. Thompson*, 347 F.3d 1335, 1349-50 (Fed. Cir. 2003). "When it comes to the veracity of patent information supplied by NDA holders, FDA operates in a purely ministerial role, relying on the NDA holders to provide the Agency with accurate patent information." *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008).

permits an ANDA applicant sued for infringement to file a counterclaim to force an Innovator to withdraw patent information. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). Teva claims that subsection (bb)(CC) is linked to the counterclaim provision and that (bb)(CC) only applies when a court has ordered an Innovator to withdraw patent information pursuant to a counterclaim. The problem with this interpretation is that the MMA contains no language linking the forfeiture provision and the counterclaim provision as Teva would prefer. The provisions simply do not refer to one another.

Moreover, even if subsection (bb)(CC) were construed in the context of the whole statute to be ambiguous, the Court would be required to defer to the FDA's interpretation under Chevron step two. It is not arbitrary or capricious for the FDA to interpret (bb)(CC) as broadly applying whenever an Innovator withdraws patent information because the statute provides no limitations on withdrawal of patent information and subsection (bb)(CC) makes no reference to the counterclaim provision.[11] The FDA's interpretation of the statute is reasonable.

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[11] Teva also argues that the FDA's interpretation of the MMA forfeiture provision permits a name brand manufacturer to manipulate the market by causing a first filing ANDA applicant to forfeit its right to exclusivity. This presumes that Merck was motivated to withdraw the '075 patent based solely on market concerns, when there is no evidence in the record regarding why Merck withdrew the patent. It could be that the patent was erroneously listed, Merck's interest in it lapsed, or Merck was required to withdraw the patent based on new FDA regulations. *See* Opp'n to Mot. for Prelim. Inj. filed by proposed intervenor Apotex, Inc. ("Apotex's Opp'n") [Dkt. # 11-6] at 19. The Court

Teva further argues that *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), applies. In *Ranbaxy*, the FDA had determined that an ANDA applicant's eligibility for the 180-day exclusive marketing period would be lost if the Innovator withdrew its patent on which the exclusivity was based and did not sue the ANDA applicant for infringement. The FDA also found that the ANDA applicant would not lose the right to exclusivity if the Innovator had sued the ANDA applicant. Ranbaxy and Teva brought suit against the FDA, arguing that the FDA could not condition eligibility for the exclusive marketing period on whether or not the Innovator had filed suit. The Circuit agreed: "[T]he FDA's requirement that a generic manufacturer's patent challenge give rise to litigation as a condition of retaining exclusivity when a patent is delisted is inconsistent with the Act, which provides that the first generic manufacturer to file an approved application is entitled to exclusivity when it either begins commercially to market its generic drug or is successful in patent litigation." *Id.* at 121.

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permits the filing of this brief on an amicus basis. *See infra*, section III.F. of this Opinion. In 2003, the FDA promulgated 21 C.F.R. § 314.53(b) which established new requirements regarding polymorph patents and the circumstances under which such patents can be said to claim a drug. The '075 patent is a polymorph patent. Teva's Mot. for Prelim. Inj. [Dkt. # 5] at 27 (the '075 patent is titled "Polymorphs of losartan and the process for the preparation of form II of losartan"). Also, Teva itself is partly responsible for the forfeiture. Teva's right to exclusivity was based only on the '075 patent because Teva filed a paragraph IV certification as to only that patent. If Teva had challenged the '069 or '197 patents, the withdrawal of the '075 patent would not have effectuated a forfeiture.

Teva reads *Ranbaxy* broadly, construing the case as overturning the FDA's interpretation of the statute because it undermined the Hatch-Waxman incentive structure. Teva reasons that this Court similarly should overturn the FDA's rule of decision set forth in the Acrabose and Cosopt Decisions for the same reason-because the FDA's interpretation of MMA subsection (bb)(CC) as applying "whenever" an NDA holder withdraws its patent also undermines the Hatch-Waxman incentive structure.

Ranbaxy was decided under the Hatch-Waxman Amendments as they existed prior to the enactment of the MMA. The Hatch-Waxman Amendments were intended both to encourage innovative new drugs and to permit the marketing of lower cost generic drugs quickly. *Tri-Bio Labs.*, 836 F.2d at 139. However, prior to the MMA, there was no provision for forfeiture of the 180-day exclusivity period. The MMA now provides that the first generic manufacturer is entitled to exclusivity if it has not forfeited that exclusivity. *See* 21 U.S.C. § 355(j)(5)(D). Thus, Congress modified the incentive structure. When enacting the MMA, Congress sought to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." *Hi-Tech*, 587 F. Supp. 2d at 4 (quoting 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (Statement of Sen. Schumer)). "Because the balance struck between these competing goals is quintessentially a matter for legislati[illegible] judgment, the court must attend closely to the terms in which Congress expressed that judgment." *Teva Pharm. Indus., Ltd. v. Crawford,*

410 F.3d 51, 54 (D.C. Cir. 2005). The FDA's interpretation of the MMA is a reasonable interpretation of the balance Congress struck between these competing goals.

F. Motion to Intervene As a Defendant

Apotex, Inc. ("Apotex") filed a motion to intervene as a defendant. *See* Dkt. # 11. Apotex filed ANDAs seeking FDA approval to market its own generic versions of losartan and losartan HCTZ products. Apotex hopes and expects that it will receive approval in time to begin marketing its products in April 2010. If Teva obtains the 180-day exclusive marketing right that it seeks in this suit, Apotex will have to sit on the sidelines for six months while Teva enjoys exclusive marketing.

An applicant may intervene as of right when the applicant (1) makes a timely motion; (2) has an interest relating to the property or transaction which is the subject of the action; (3) is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest; and (4) where the applicant's interests are not adequately represented by the existing parties. Fed. R. Civ. P. 24(a)(2); *see also Sierra Club v. Van Antwerp*, 523 F.Supp.2d 5, 6 (D.D.C. 2007). Article III standing is required for intervention under Rule 24(a)(2). *S. Christian Leadership Conference v. Kelley*, 747 F.2d 777, 779 (D.C. Cir. 1984). To demonstrate standing, a party must establish: "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly

traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth*, 528 U.S. at 180-81, 120 S.Ct. 693 (citing *Lujan*, 504 U.S. at 560-61).

Apotex asserts that its ANDAs are under review by the FDA and it expects to receive final approval to begin marketing on April 6, 2010. Apotex's expectation of final approval depends on the FDA's completion of scientific review of Apotex's ANDAs and finding no deficiencies in the ANDAs. The interest that Apotex alleges in this suit-its desire to market generic losartan in the future-presumes final approval of its ANDAs and is speculative.[12] Thus, Apotex's motion to intervene as of right will be denied.

A court may grant permissive intervention where the applicant: (1) makes a timely motion; (2) has a claim or defense; and (3) that claim or defense shares with the main action a common question of law or fact. Fed. R. Civ. P. 24(b). The requirements for

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[12] The Hatch-Waxman Amendments provide that the FDA may grant a tentative approval notifying an applicant that the ANDA meets scientific standards but cannot receive final approval until some patent barrier or other regulatory barrier (such as the exclusivity period) is overcome. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); *id.* § 355(j)(2)(a); 21 C.F.R. § 314.105(d). Final approval may be granted when an applicant has met the scientific standards for approval and the patent and regulatory barriers no longer apply. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); *id.* § 355(j)(2)(a); 21 C.F.R. § 314.105(d). The FDA has granted tentative approval to Teva's ANDAs but not to those submitted by Apotex.

permissive intervention are construed liberally in favor of intervention in special cases. *Equal Employment Opportunity Comm'n v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998). The decision whether to grant permissive intervention is discretionary. *In re Vitamins Antitrust Class Actions*, 215 F.3d 26, 32 (D.C. Cir. 2000).[13] Apotex's interest in this suit is a speculative business interest, i.e., a desire to enter the generic losartan market earlier rather than later. Apotex presumes that the FDA will approve its ANDAs at some point. Under these circumstances, Apotex's interest does not warrant intervention, and the Court will deny Apotex's request to intervene. However, the Court will permit Apotex to file, as amicus curiae, its opposition to preliminary injunction, which the Court has considered. See *Firestone Tire & Rubber Co. v. PBGC*, 695 F. Supp. 43, 44 (D.D.C. 1988) (the decision to appoint an amicus rests within the broad discretion of the district court).

IV. CONCLUSION

For the reasons stated above, the FDA's motion to dismiss [Dkt. # 9] will be denied. Teva's motion for preliminary injunction [Dkt. # 5] is consolidated with trial on the merits pursuant to Federal Rule of Civil Procedure 65(a)(2), and judgment will be entered in favor of the FDA. Further, the motion to intervene as a defendant filed by Apotex [Dkt. # 11] will be denied,

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[13] There is uncertainty under D.C. Circuit law whether standing is required for permissive intervention. *In re Vitamins Antitrust Class Actions*, 215 F.3d at 31-32.

but the Court will permit Apotex to file, as amicus curiae, the opposition to preliminary injunction set forth as Exhibit 5 to Apotex's motion to intervene [Dkt. # 11-6]. A memorializing order accompanies this Memorandum Opinion.

Date: July 31, 2009

Rosemary Collyer

United States District Judge

APPENDIX F

STATUTORY PROVISIONS

21 U.S.C. § 355(j)(2)(A)(vii)

(j) Abbreviated new drug applications

* * *

(2)(A) An abbreviated application for a new drug shall contain –

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section –

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]

21 U.S.C. § 355(j)(5)(B)(i), (iv)

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

> (i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

* * *

> (iv) 180-day exclusivity period
>
> > (I) Effectiveness of application Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.
> >
> > (II) Definitions
> >
> > In this paragraph:
> >
> > > (aa) 180-day exclusivity period The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period

of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

21 U.S.C. § 355(j)(5)(D)

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market The first applicant fails to market the drug by the later of –

(aa) the earlier of the date that is –

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with

respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner.

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

* * *

No. 10-453

In the Supreme Court of the United States

APOTEX, INC., PETITIONER

v.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

NEAL KUMAR KATYAL
Acting Solicitor General
Counsel of Record
TONY WEST
Assistant Attorney General
DOUGLAS N. LETTER
CHRISTINE N. KOHL
Attorneys
Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

Whether an applicant seeking to market a generic drug may forfeit marketing exclusivity under 21 U.S.C. 355(j)(5)(D) based on unilateral action by the holder of a patent the applicant has certified is invalid or not infringed by the drug.

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In the Supreme Court of the United States

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BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-3a) is unreported. The opinion of the district court (Pet. App. 4a-11a) is reported at 700 F. Supp. 2d 138.

JURISDICTION

The judgment of the court of appeals was entered on July 6, 2010. The petition for a writ of certiorari was filed on October 4, 2010. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), Pub. L. No. 98-417, 98 Stat. 1585, amended the Federal

Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, to make it easier for manufacturers of generic versions of brand-name drugs to enter the market, thereby increasing competition and lowering prices for consumers.

a. A brand-name drug is typically approved by the Food and Drug Administration (FDA) based on a new drug application (NDA). See 21 U.S.C. 355(b)(1). Once approved, FDA lists the drug in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book. See 21 U.S.C. 355(j)(7)(A)(i)(I), (ii). Thereafter, any manufacturer may seek approval to market a generic version under the Hatch-Waxman Amendments, which prescribe a process of submitting an abbreviated new drug application (ANDA) for a generic drug. See 21 U.S.C. 355(j).

At the time the NDA is approved, patents held by (or licensed to) the brand-name drug's manufacturer will often preclude production and marketing of a generic version by another manufacturer. Accordingly, the Hatch-Waxman Amendments provide that an NDA applicant "shall file with the [NDA] the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. 355(b)(1). Conversely, the NDA applicant may not file patent information that does not meet this standard. See Pet. App. 28a n.14. The required patent information is published by FDA in the Orange Book entry for the brand-name drug. 21 U.S.C. 355(j)(7)(A). FDA updates the Orange Book when new patent infor-

mation is submitted. 21 U.S.C. 355(j)(7)(A)(iii). FDA does not investigate patent information or correct it in the Orange Book unless and until the NDA holder confirms the correction. 21 C.F.R. 314.53(f); see *Teva Pharm., USA, Inc.* v. *Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) (recognizing FDA's "purely ministerial role" respecting "the veracity of the patent information supplied by NDA holders").

An ANDA generally must contain one of four certifications respecting each patent that claims the drug (or a use for the drug) for which the ANDA applicant seeks approval to market a generic equivalent: (I) the patent information has not been filed with FDA; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. 21 U.S.C. 355(j)(2)(A)(vii)(I)-(IV). These certifications are commonly referred to by their statutory paragraph numbers. Paragraph I and paragraph II certifications do not delay FDA's approval of the ANDA. See 21 U.S.C. 355(j)(5)(B)(i). A paragraph III certification delays FDA's final approval until the patent's expiration date. See 21 U.S.C. 355(j)(5)(B)(ii). A paragraph IV certification is an act of patent infringement, see 35 U.S.C. 271(e)(2)(A), and thus carries the risk of litigation by the patent holder or the NDA applicant against the ANDA applicant. FDA will grant "tentative approval" to an ANDA that meets the substantive requirements for approval under 21 U.S.C. 355(j)(2)(A), but which cannot be finally approved because of an unexpired patent subject to a paragraph III certification, because of a paragraph IV certification, or because of certain NDA

exclusivity periods not relevant here. See 21 U.S.C. 355(j)(5)(B)(iv)(II)(dd)(AA).

b. The Hatch-Waxman Amendments facilitate the entry of generic drugs into the market by encouraging challenges to weak or invalid patents, and by encouraging ANDA applicants to devise generic equivalents that do not infringe patents listed in the Orange Book. The Amendments do so by generally rewarding the first ANDA applicant that files a paragrap. IV certification with a 180-day period of marketing exclusivity upon approval of its ANDA. That period is implemented by delaying FDA's final approval of any subsequent ANDA with a paragraph IV certification covering that patent.

Before 2003, FDA could not finally approve any subsequent ANDA that contained a paragraph IV certification until 180 days after the earlier of (I) FDA's receipt of a notice from the first ANDA applicant of the first commercial marketing of the generic drug by that applicant (*i.e.*, the start of the marketing exclusivity period), or (II) the date of a court decision holding that the patent subject to the paragraph IV certification is invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iv) (2000). But brand-name and generic drug manufacturers "abused this exclusivity period—both through collusive agreements and use of other tactics that allow[ed] the [180-day] provision to act as a bottleneck to generic competition." 149 Cong. Rec. 31,200 (2003) (Sen. Schumer). For example, NDA holders paid first ANDA applicants to "park" their exclusivity, thereby deferring their entry into the market and giving the NDA holders longer marketing periods with no competition. See generally *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 535 U.S. 931 (2002).

To thwart such abuses, Congress enacted Section 1102 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2457. The MMA adheres to the basic rule that FDA may not approve any subsequent ANDA with a paragraph IV certification until 180 days after the first commercial marketing of the drug by the first ANDA applicant. See 21 U.S.C. 355(j)(5)(B)(iv)(I). But the MMA amended the generic exclusivity provision in two respects relevant here. First, the MMA defines a "first applicant" entitled to 180 days of marketing exclusivity as an applicant that, *inter alia*, "lawfully maintains" a paragraph IV certification for the drug in question. 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb).

Second, the MMA makes the exclusivity period "[s]ubject to subparagraph (D)." 21 U.S.C. 355(j)(5)(B)(iv)(I). Subparagraph (D) specifies six events, each of which results in the forfeiture of exclusivity by the first applicant with a paragraph IV certification. See 21 U.S.C. 355(j)(5)(D). Two are relevant here. One forfeiture event, aimed directly at the parking of exclusivity, is the "[f]ailure to market" the generic drug within 75 days after (a) a court issues a decision "[i]n an infringement action" holding the patent invalid or not infringed, (b) "an infringement action" settles and includes a court finding that the patent is invalid or not infringed, or (c) "[t]he patent information * * * is withdrawn by the holder of the [NDA]." 21 U.S.C. 355(j)(5)(D)(i)(I). The last of these, withdrawal of patent information "by the holder of the [NDA]," 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC), is referred to as "delisting," because a withdrawal request by the NDA holder causes FDA to remove the patent listing from the Orange Book. Another forfeiture event is the "[e]xpiration of all pat-

ents" as to which a paragraph IV certification has been submitted. 21 U.S.C. 355(j)(5)(D)(i)(VI).[1]

The MMA thus "restructure[d] how the 180-day generic exclusivity provisions work" by limiting eligibility for exclusivity. 149 Cong. Rec. at 31,783 (Sen. Kennedy). A first applicant otherwise entitled to marketing exclusivity can now lose its eligibility for that exclusivity if any of the statutory forfeiture events occurs. And when a first applicant loses exclusivity, "no applicant shall be eligible for * * * exclusivity." 21 U.S.C. 355(j)(5)(D)(iii)(II). Under those circumstances, any ANDA is potentially eligible for immediate approval, which would provide consumers with more generic drugs sooner. See 149 Cong. Rec. at 31,200 (Sen. Schumer).

2. a. In 2003 and 2004, respondent Teva Pharmaceuticals USA, Inc. (Teva), filed two ANDAs, seeking FDA approval for generic versions of two losartan drugs marketed by Merck to treat hypertension, Cozaar® and Hyzaar®. Teva's ANDAs contained paragraph IV certifications with respect to Merck patent No. 5,608,075 (the '075 patent). Merck did not sue Teva (or any other losartan ANDA applicant) for infringement. But Merck asked FDA to delist the '075 patent from the Orange Book, and FDA did so in April 2008. Gov't C.A. Br. 6-7.

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[1] The other forfeiture events are: the first applicant's withdrawal of its ANDA (including constructive withdrawal, where FDA has determined that it does not meet the requirements for approval); the first applicant's amendment or withdrawal of its paragraph IV certification(s); the first applicant's failure to obtain tentative approval within 30 months of the filing of its ANDA; and a final judicial or administrative finding that an agreement between the first applicant and another ANDA applicant, the NDA holder, or the patent owner violates the antitrust laws. See 21 U.S.C. 355(j)(5)(D)(i)(II)-(V).

FDA granted tentative approval to Teva's ANDAs in 2006 and 2007. Although FDA does not identify which ANDA is first-filed in advance of final approval, see 21 C.F.R. 314.430(b), Teva believed that its ANDAs were the first-filed ones containing paragraph IV certifications to the '075 patent. Teva thus expected to receive a 180-day period of marketing exclusivity upon final approvals of its ANDAs. But Teva feared that the delisting of the '075 patent would cause FDA to deny it exclusivity, given FDA's action in two previous decisions involving different drugs and different companies that failed to market their products within 75 days after the delisting of the patents that were subject to their paragraph IV certifications. Gov't C.A. Br. 7.

Without awaiting FDA's final action on its pending ANDAs, Teva filed suit in the United States District Court for the District of Columbia in June 2009, challenging FDA's interpretation of the delisting forfeiture provision (as set forth in the two earlier FDA decisions) and seeking a declaration that Teva had not forfeited exclusivity. Although the district court rejected FDA's arguments that the case was unripe, Teva lacked standing, and there was no final agency action, the district court nonetheless upheld FDA's interpretation of the statute, finding the delisting forfeiture provision unambiguous. *Teva Pharms. USA, Inc.* v. *Sebelius*, 638 F. Supp. 2d 42 (D.D.C. 2009) (Pet. App. 72a-106a).

b. Teva appealed, and a divided panel of the court of appeals reversed and remanded. *Teva Pharm. USA, Inc.* v. *Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010) (*Teva*) (Pet. App. 31a-71a). The court of appeals first held that, although FDA had not yet taken final action on Teva's ANDAs, Teva's action was ripe for review and Teva had standing to challenge FDA's interpretation of the

delisting forfeiture provision, as set forth in FDA's two earlier decisions. Pet. App. 42a-56a. Finding it "virtually inconceivable" that any event other than delisting could deprive Teva of exclusivity, the panel majority stated that, based on the earlier decisions, "we know precisely what the FDA thinks the answer is; and its resolution will almost certainly determine whether Teva is entitled to the exclusivity it claims." *Id.* at 45a. Judge Henderson dissented on the ground that Teva's action was not yet ripe for review. She explained that "FDA may conclude Teva forfeited its eligibility upon Merck's delisting of its patents, * * * or it may reject Teva's application [for marketing exclusivity] based on one of the other forfeiture provisions." *Id.* at 69a.

The court of appeals next addressed Teva's arguments on the merits about why the delisting of the '075 patent should not deprive it of exclusivity. Teva invoked 21 U.S.C. 355(j)(5)(C)(ii)(I), which was added by the MMA and which authorizes an ANDA applicant sued in an infringement action to counterclaim for "an order requiring the [NDA] holder to correct or delete the [pertinent] patent information" on the ground that "the patent does not claim either * * * the drug" subject to the NDA or "an approved method of using the drug." Teva argued that, because that is the only provision in the FDCA that provides for delisting a patent subject to a paragraph IV certification, it "describes *the only scenario* in which the FDA may delist a challenged patent," and, therefore, no other kind of delisting could result in a "failure to market" forfeiture of exclusivity under 21 U.S.C. 355(j)(5)(D)(i)(I). Pet. App. 58a.

Although the panel majority found this "linguistic argument" to be "plausible," it could not rule out "alternative readings that, absent consideration of statutory

structure, also appear plausible." Pet. App. 58a. The court of appeals explained that, as FDA had noted, nothing in the statute precludes delistings outside the counterclaim scenario, or the triggering of a forfeiture event by such a delisting. *Id.* at 58a-59a.

The court of appeals then turned to Teva's argument based on what Teva asserted was the "incentive structure" of the Hatch-Waxman Amendments. See Pet. App. 59a. The court explained that, setting aside delisting, "the 'failure to market' forfeiture provision does not permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter." *Id.* at 61a. Relying on a decision that interpreted the statute as it existed before the MMA, the court of appeals found "*not a single cogent reason*" why Congress would have "explicitly provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity * * * by withdrawing a challenged patent, outside the counterclaim scenario identified by Teva." *Id.* at 62a (citing *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)). The Court therefore concluded that "nothing in the [MMA] * * * changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve." *Id.* at 64a.

The court of appeals thus held that FDA's interpretation of the delisting forfeiture provision "fails at *Chevron* step one" because it found that interpretation to be inconsistent with the statute's structure. Pet. App. 64a; see *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 842 (1984) (at step one of the two-part analysis of an agency's interpretation of a statute it administers, if "Con-

gress has directly spoken to the precise question at issue," and "the intent of Congress is clear, that is the end of the matter").

3. A few days after the court of appeals issued its decision in the *Teva* case, in a turn of events the court of appeals had described as "virtually inconceivable," Pet. App. 45a, petitioner notified FDA that it had just discovered that the '075 patent had expired more than a year earlier (and several months before Teva had filed suit) due to the nonpayment of patent fees. See 35 U.S.C. 41(b) (unless the Patent and Trademark Office receives payment of the fee as prescribed by law, "the patent will expire as of the end of [a six-month] grace period."). FDA immediately requested confirmation from Merck that the '075 patent had expired. After receiving Merck's confirmation that the patent had expired on March 4, 2009, FDA updated the Orange Book with that information. Pet. App. 13a & n.1. FDA also solicited public comment on whether the expiration of the '075 patent was a separate basis for the forfeiture of exclusivity for generic versions of losartan. *Id.* at 16a; see 21 U.S.C. 355(j)(5)(D)(i)(VI).

In a decision issued on March 26, 2010, FDA addressed the effect of patent expiration on exclusivity. Pet. App. 12a-30a. At the outset, FDA noted that its usual practice is to render exclusivity determinations contemporaneously with granting final approval of an ANDA. FDA explained that it was departing from that practice because of the "exceptional circumstances" of this case, including the significant active litigation and the approaching date of April 6, 2010, when the last patent on Cozaar® and Hyzaar® subject to a paragraph III certification (*i.e.*, not the '075 patent) was due to expire,

making one or more ANDAs eligible for final approval. *Id.* at 16a n.6.

On the merits, FDA explained that one of the forfeiture events specifically defined in the statute is "Expiration of all patents," 21 U.S.C. 355(j)(5)(D)(i)(VI), and, "[i]f this forfeiture event applies to a first applicant, the applicant forfeits exclusivity immediately upon the expiration of all patents as to which it qualified as a first applicant." Pet. App. 18a. FDA noted that, under its "longstanding interpretation," which pre-dated even the MMA, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished," and "the correct certification to the patent is a 'paragraph II' certification." *Id.* at 19a-20a; see 21 U.S.C. 355(j)(2)(A)(vii)(II) ("such patent has expired"). In turn, if an ANDA no longer contains a paragraph IV certification, "the applicant no longer has a basis to obtain exclusivity as to that patent." Pet. App. 20a. FDA pointed out that courts have upheld that interpretation of the statute as reasonable and have accepted the principle that "the first generic applicant may no longer retain exclusivity when the patent has expired." *Ibid.* (quoting *Ranbaxy*, 469 F.3d at 126 n.*).

As to the MMA's provision for forfeiture of exclusivity upon patent expiration, FDA concluded that it "embodie[d] the familiar [pre-MMA] principle that 180-day exclusivity does not survive patent expiration." Pet. App. 20a. FDA emphasized, however, that the issue presented by the expiration of the '075 patent in this case "is not whether, as a general rule, exclusivity will be forfeited" under the MMA amendments any time a patent expires, but instead "whether a patent expiration for failure to pay fees is an exception to this rule." *Id.* at 21a. Based on "the plain meaning of the words of the

statute," FDA found no such exception and concluded that patent expiration "for any reason" is a forfeiture event under 21 U.S.C. 355(j)(5)(D)(i)(VI). Pet. App. 21a. FDA reasoned that, because the text of the patent-expiration forfeiture provision contains no qualifying language, it provides no basis "to distinguish between 'natural patent expiry' and expiration for some other reason." *Ibid.*[2]

FDA noted further that patent expiration "also necessitates a change in the ANDA applicants' patent certifications" because, "[u]pon expiration of a patent, a paragraph IV certification to the patent automatically becomes invalid." Pet. App. 25a (citing *Ranbaxy Labs. Ltd.* v. *FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (affirming 307 F. Supp. 2d 15 (D.D.C. 2004))). FDA therefore concluded that "a paragraph IV certification to the expired '075 patent is invalid, and the appropriate certification to the patent is 'paragraph II.'" *Ibid.* FDA further concluded that if a first applicant's ANDA no longer contains a valid paragraph IV certification, the 180-day exclusivity provision, "by its own terms, does not apply." *Ibid.*; see 21 U.S.C. 355(j)(5)(B)(iv)(I); see also 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb) ("first applicant" is an applicant that "lawfully maintains" a paragraph IV certification). Thus, "permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute."

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[2] FDA acknowledged the possibility that a patent that has expired for nonpayment of fees could be revived in certain circumstances, but it concluded that such a possibility was "an inadequate basis to maintain that a later expiration date must control." Pet. App. 22a. As the agency explained, it relies on the NDA holder to notify it of the patent expiration date; when an NDA holder has done so, it is reasonable to presume the finality of the patent expiration. *Id.* at 22a-23a.

Pet. App. 25a. FDA further explained that even if the statutory language is ambiguous, it would still conclude that the forfeiture of exclusivity in this circumstance is "most consistent with the statute's text and goals, and provides the most reasonable way of administering the statute." *Id.* at 26a.

Nevertheless, despite those conclusions based on the statutory text, FDA determined that it was obliged to consider the *Teva* decision in determining whether the expiration of the '075 patent for nonpayment of fees triggered a forfeiture of exclusivity. Pet. App. 26a. The agency noted that the court of appeals' ruling in *Teva* was at "'*Chevron* step one,'" that is, "there was no statutory ambiguity that FDA is free to resolve based on its understanding of the statute and the industry it regulates." *Id.* at 27a (quoting *id.* at 64a). FDA then explained that, notwithstanding the text of the MMA, *id.* at 26a, the *Teva* court held that the statute's "structure * * * does not permit an NDA holder to 'unilaterally' deprive the generic applicant of its exclusivity on the basis of delisting," *id.* at 27a. In FDA's view,

> [*Teva*] appears to preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder. Because the '075 patent expired due to Merck's failure to pay applicable fees, that expiration, consistent with the Court of Appeals' reasoning in *Teva*, is not a ground[] for forfeiture of the first applicant's exclusivity.

Id. at 28a.

FDA reserved its right to revisit the issue, if the court of appeals granted the agency's then-pending petition for rehearing en banc in *Teva* and revised its ruling.

Pet. App. 28a. The court of appeals later denied rehearing en banc in *Teva*. *Teva*, *supra*, No. 09-5281 (D.C. Cir. May 17, 2010).

4. a. Petitioner and another generic drug manufacturer, both of which had received tentative approval for their ANDAs for losartan drugs, challenged FDA's patent expiration decision in the United States District Court for the District of the District of Columbia. Teva intervened as a defendant. The district court denied petitioner's motion for a preliminary injunction, concluding that "FDA properly followed the logic of the D.C. Circuit's decision in *Teva*," Pet App. 11a, and thus petitioner "ha[d] a very slim chance of success on the merits," *id.* at 9a. The district court also found that petitioner failed to satisfy the other criteria for preliminary injunctive relief. *Id.* at 10a-11a. The district court has since stayed further proceedings pending disposition of the certiorari petition in this Court.

b. Petitioner appealed from the denial of preliminary injunctive relief and sought a stay. The court of appeals denied the stay motion on April 6, 2010, and on the same day, FDA granted final approval to Teva's losartan ANDAs and advised Teva that it was eligible for 180 days of marketing exclusivity. Teva began marketing its losartan drugs almost immediately, and its period of exclusivity ended on October 4, 2010. See 21 U.S.C. 355(j)(5)(B)(iv)(I).

c. The court of appeals affirmed in a per curiam order. Pet. App. 1a-3a. Relying on its decision in *Teva*, 595 F.3d at 1317-1318, the court of appeals explained:

> When the Hatch-Waxman Act's forfeiture provisions are viewed in the context of the statute's incentive structure, it becomes clear that Congress could not have intended a brand manufacturer's unilateral de-

cision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute.

Pet. App. 2a-3a.

ARGUMENT

The court of appeals held that an NDA holder's unilateral action—in *Teva*, delisting a patent subject to a paragraph IV certification, and here, allowing such a patent to expire for nonpayment of fees—is not a basis for forfeiture of the first ANDA applicant's presumptive 180-day period of marketing exclusivity. The court based that conclusion not on the text of the FDCA, but instead on what it believed to be the Hatch-Waxman Amendments' "incentive structure." The court of appeals' methodology, reasoning, and holding are incorrect. The MMA was enacted to adjust the balance between exclusivity and full generic competition—a central objective the court of appeals failed even to acknowledge. The MMA achieves its goal through the carefully crafted provisions for forfeiture of exclusivity. There is no textual basis in those provisions or elsewhere in the FDCA for the court of appeals' conclusion; indeed, the statutory text directly contradicts the court of appeals' holding below and its holding in *Teva*.

Notwithstanding the court of appeals' errors and the significant adverse consequences its rulings have had for consumers, this Court should defer review of the question presented. FDA has applied the MMA's forfeiture provisions on only a few occasions, and the D.C. Circuit is the only court of appeals to have construed those provisions. If future controversies materialize, they are

likely to be heard by another court of appeals, giving the Court greater assurance that the question presented is of recurring significance and the legal issues have fully percolated in lower courts. Accordingly, the Court should deny the petition for a writ of certiorari.

A. The court of appeals' decision is incorrect. It fails to respect the FDCA's statutory text and the backdrop against which Congress enacted the MMA. Instead, it places unwarranted reliance on a misperception that forfeitures resulting from unilateral action by the NDA holder are irreconcilable with the Hatch-Waxman Amendments' incentive structure.

1. As FDA's decision explains, Pet. App. 18a, the statute explicitly addresses "Expiration of all patents," and its text is clear: a "forfeiture event" occurs when "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired." 21 U.S.C. 355(j)(5)(D)(i)(VI). And "[t]he 180-day exclusivity period * * * shall be forfeited by a first applicant if a forfeiture event occurs." 21 U.S.C. 355(j)(5)(D)(ii). The straightforward wording of the statute treats all expired patents equally.

In particular, the forfeiture provision has no qualifying language that would suggest that only some patent expirations result in a forfeiture, or that a patent can "expire" within the meaning of 21 U.S.C. 355(j)(5)(D)(i)(VI) only on the date established when the patent issued, or that patent expiration due to nonpayment of fees is not a patent expiration forfeiture event. To be sure, the FDCA does not explicitly address the precise question whether patent expiration due to nonpayment of fees is a forfeiture event. But "the fact that a statute can be applied in situations not expressly anticipated by Congress * * * demonstrates breadth."

Pennsylvania. Dep't of Corr. v. *Yeskey*, 524 U.S. 206, 212 (1998) (citation and internal quotation marks omitted).

The statute likewise contains no limitations on who or what must trigger a patent expiration in order for it to qualify as a forfeiture event. Thus, the fact that a patent expires as the result of unilateral action by the patent holder—*e.g.*, the decision not to pay maintenance fees, see 35 U.S.C. 41(b), -is irrelevant. Instead, the focus of this forfeiture provision is simply the status of the patent that is the subject of a paragraph IV certification. That is necessarily so because the continued existence of such a patent is the *sine qua non* of generic marketing exclusivity, as the FDCA makes clear. Only the first applicant with a paragraph IV certification is entitled to exclusivity, and the "first applicant" must "lawfully maintain[] [that] certification." 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb).

2. The MMA's exclusivity forfeiture scheme is in harmony with—and thus represents congressional ratification and codification of—FDA's longstanding understanding of the relationship between patent expiration and forfeiture of exclusivity.

FDA's pre-MMA position was that, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished." Pet. App. 19a. Pursuant to an FDA regulation originally adopted in 1994, "an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate." 21 C.F.R. 314.94(a)(12)(viii)(C)(*1*). Thus, for example, FDA explained in a 1999 decision that, upon expiration of a patent subject to a paragraph IV certification, the ANDA applicant must change

its certification to a paragraph II certification stating that "such patent has expired," 21 U.S.C. 355(j)(2)(A)(vii)(II). See *Dr. Reddy's Labs., Inc.* v. *Thompson*, 302 F. Supp. 2d 340, 357 (D.N.J. 2003). The consequence of such a change is that "eligibility for exclusivity does not extend beyond the expiration of [the] patent." *Ibid.* The court in *Dr. Reddy's* upheld that FDA interpretation of the statute, *id.* at 356-357, as have numerous appellate decisions. See *Teva Pharms., USA, Inc.* v. *Leavitt*, 548 F.3d 103, 107 (D.C. Cir. 2008); *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120, 126 n.* (D.C. Cir. 2006); *Mylan Labs., Inc.* v. *Thompson*, 389 F.3d 1272, 1282-1283 (D.C. Cir. 2004); *Ranbaxy Labs. Ltd.* v. *FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (affirming 307 F. Supp. 2d 15, 19-20, 21 (D.D.C. 2004)).

Congress is presumed to have been aware of FDA's regulation and longstanding interpretation when it enacted the forfeiture provisions. See *Lorillard* v. *Pons*, 434 U.S. 575, 580 (1978). It is likewise presumed that, when Congress enacts legislation, it is aware of other existing laws, such as the provision of patent law providing that a "patent will expire" for nonpayment of maintenance fees, 35 U.S.C. 41(b) (added by Act of Dec. 12, 1980, Pub. L. No. 96-517, § 2, 94 Stat. 3017). See *South Dakota* v. *Yankton Sioux Tribe*, 522 U.S. 329, 351 (1998).

It is therefore most natural to conclude that when Congress declared "[e]xpiration of all patents" to be a forfeiture event, it understood that (i) patents could expire not only on their original, specified dates of expiration, but also on earlier dates due to nonpayment of fees; (ii) under FDA regulations, patent expiration would require an ANDA applicant to change its paragraph IV certification; and (iii) elimination of such a certification

would necessarily result in the loss of a first applicant's eligibility for exclusivity. Against that backdrop, Congress enacted the MMA, which added both the experss patent expiration forfeiture provision and the requirement that a first applicant "lawfully maintain[]" a paragraph IV certification in order to qualify for exclusivity. 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb).

FDA therefore reasonably concluded that, putting the court of appeals' *Teva* decision to one side, "because the '075 patent will have expired by the time any ANDA referencing Cozaar or Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity." Pet. App. 26a.

3. For similar reasons, the D.C. Circuit's *Teva* decision on forfeiture due to a failure to market following a delisting fails to respect the statutory text.

Delisting appears in the FDCA as part of the calculus in the failure-to-market forfeiture provision. See 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC). Although the failure-to-market forfeiture provision is densely worded and somewhat complex, there was no dispute in *Teva* that the forfeiture question came down to whether delisting of the '075 patent satisfied Subitem (CC). See Pet. App. 38a-41a & n.2. Like the patent expiration event discussed above, the delisting event described in Subitem (CC) is unconditional: it occurs when "[t]he patent information submitted [by the NDA holder] is withdrawn by the [NDA holder]."

That text reveals no intent to exclude from its reach delisting at the instance of the NDA holder. Indeed, if Subitem (CC) has any qualification, it is that *only* delisting "by the [NDA] holder" qualifies. 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC). That reflects the fact that

only the NDA holder has the authority to delist a patent referred to in connection with its NDA, and it must do so when a patent fails to meet the standard stated in 21 U.S.C. 355(b)(1). See p. 5, *supra*; see also 21 U.S.C. 355(j)(5)(C)(ii)(I) (describing court "order requiring the [NDA] holder to correct or delete [certain] patent information"); 21 C.F.R. 314.53(a) ("*Who must submit patent information.* This section applies to any applicant who submits to FDA [an NDA]."); 21 C.F.R. 314.70(f) ("The [NDA holder] must comply with the patent information requirements under [21 U.S.C. 355(c)(2)].").

Nor does that text suggest that forfeiture of exclusivity can be triggered only by a delisting that was ordered as a remedy for a counterclaim in an infringement action, see 21 U.S.C. 355(j)(5)(C)(ii)(I), as Teva had proposed to the court of appeals, see Pet. App. 57a-59a. To the contrary, in contrast to the neighboring Subitems (AA) and (BB), the event described in Subitem (CC) need not occur in circumstances arising from "an infringement action." 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(AA), (BB). When Congress includes particular language in one section of a statute but omits it in another, it is generally presumed that Congress has acted intentionally. See, *e.g.*, *Barnhart* v. *Sigmon Coal Co.*, 534 U.S. 438, 452 (2002).

The FDCA's text thus belies the court of appeals' conclusion in *Teva* and the decision below that Congress could not have intended that a brand-name manufacturer's "unilateral" decision "strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute." Pet. App. 3a (citation omitted).

4. The court of appeals did not premise *Teva* or the decision below on the statutory text. It relied instead on what it believed to be "the statute's incentive structure."

Pet. App. 2a. The court of appeals was wrong to rely on its perception of the statute's "incentive structure" to displace the statutory text, and in any event, the court misunderstood the FDCA's post-MMA incentive structure.

The decision below relies on *Teva*'s understanding of the Hatch-Waxman Amendment's incentive structure, which in turn relied on the court of appeals' pre-MMA decision in *Ranbaxy*. *Ranbaxy* disapproved an FDA interpretation of the Hatch-Waxman Amendments that would have denied exclusivity to a first applicant if the NDA holder responded to a paragraph IV certification by delisting the patent at issue. See 469 F.3d at 125-126. *Ranbaxy* suggested that FDA's interpretation was impermissible because, *inter alia*, it would "reduc[e] the [first applicant's] certainty of receiving a period of marketing exclusivity" and therefore "diminish[ ] the incentive for a manufacturer of generic drugs to challenge a patent." Pet. App. 59a (quoting *Ranbaxy*, 469 F.3d at 126). The court of appeals in *Teva* saw "nothing specific [in the MMA forfeiture provisions] to undermine [*Ranbaxy*'s] understanding of the statute's intended incentive structure." *Id.* at 60a. That analysis is seriously flawed in several respects.

a. At the most basic level, the court of appeals offered no support (besides *Ranbaxy* itself) for the proposition that gestalt notions of a statute's "incentive structure" should prevail over Congress's precise instructions in the text of a reticulated statutory scheme like the Hatch-Waxman Amendments. As this Court has repeatedly held, "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Arlington Cent. Sch. Dist. Bd. of Educ.* v. *Murphy*, 548 U.S. 291, 296 (2006) (quoting *Connecti-*

cut Nat'l Bank v. *Germain*, 503 U.S. 249, 253-254 (1992)).

b. The court of appeals further erred in concluding that "nothing" in the 2003 MMA amendments altered the incentive structure of the Hatch-Waxman Amendments. Pet. App. 59a-60a, 64a. The *very purpose* of the MMA was to rebalance the incentive structure of the statute to address abuses of the exclusivity period—by both brand-name and generic manufacturers—that had created "bottleneck[s] to generic competition." 149 Cong. Rec. at 31,200 (Sen. Schumer). Indeed, the addition of six separate forfeiture events is incontrovertible evidence that Congress intended to "reduc[e] the [first applicant's] certainty of receiving a period of marketing exclusivity." Pet. App. 59a (quoting *Ranbaxy*, 469 F.3d at 126). Congress did so to encourage full competition among generic manufacturers and limit the exclusivity available to a first applicant. See 149 Cong. Rec. at 31,783 (Sen. Kennedy) (explaining that the MMA "restructures how the 180-day generic exclusivity provisions work").

Yet the court of appeals' "incentive structure" reasoning nullifies parts of the MMA's forfeiture framework. For example, the court of appeals suggested that Congress intended that a first applicant forfeit its exclusivity only when it "had some say in the matter." Pet. App. 61a. But rarely (if ever) would the first applicant "ha[ve] some say in" when a NDA holder's patents expire, see 21 U.S.C. 355(j)(5)(D)(i)(VI), so it is unclear when (if ever) that provision should operate. Moreover, the court of appeals in *Teva* effectively limited exclusivity forfeiture due to a patent's delisting under 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(CC) to the counterclaim scenario described in 21 U.S.C. 355(j)(5)(C)(ii)(I). Yet the order

described in 21 U.S.C. 355(j)(5)(C)(ii)(I) would be accompanied by a judgment of invalidity or non-infringement that would *independently* trigger 21 U.S.C. 355(j)(5)(D)(i)(I)(bb)(AA) or (BB), rendering Subitem (CC) superfluous. Such incongruities place the court of appeals' decisions in considerable tension with the well established principle that Congress is presumed to intend that every word in a statute—not to mention each discrete provision—have meaning and effect. See, *e.g.*, *Mountain States Tel. & Tel. Co.* v. *Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985).

c. Independently of those two errors, the court of appeals also misunderstood the economic incentives at work. In particular, it assumed that an NDA holder would be economically motivated to thwart a first applicant's exclusivity by delisting (or allowing the premature expiration of) the patent as to which the first applicant had submitted a paragraph IV certification. Based on that assumption, the court of appeals believed that Congress could not have intended such "unilateral" action to factor into the statute's incentive structure. Pet. App. 3a, 61a-63a.

But the court's assumption about NDA holders' economic motives was mistaken: As petitioner explains (Pet. 21), if the first applicant retains exclusivity, it and the NDA holder enjoy 180 days of duopoly, during which the generic product is on average priced only about six percent below the brand-name product. When a second generic manufacturer enters the market (because the first applicant's exclusivity has ended or has been forfeited), the generic drugs' prices are generally almost 50% below the brand-name drug's price. Further decreases in price—with corresponding increases in bene-

fits for consumers—follow as more generic manufacturers enter the market.

The NDA holder thus derives no obvious gain in sales or profit from facilitating earlier full generic competition by causing the first applicant to forfeit exclusivity. Indeed, the brand-name manufacturer may lose more sales sooner by triggering a forfeiture event, because a brand-name manufacturer (which will typically continue to demand a high price for its product even after generic entry) is likely to fare better during a period of exclusivity with only one competitor priced slightly below it, than it would if it were competing against multiple generic competitors priced significantly below it. Of course, NDA holders do on occasion "unilaterally" cause a first applicant to forfeit exclusivity. But an NDA holder that delists a patent may simply have determined that its original filing of patent information had in fact not met the standard required by 21 U.S.C. 355(b)(1) and related provisions. As FDA explained in its decision in this case, such delistings may well reflect "considerations of antitrust liability" for the competition-blocking effects of patent listing, or the settlement of actions brought by the Federal Trade Commission. Pet. App. 28a n.14; see Pet. 34 n.13.

That same misunderstanding of the economics of generic entry may also explain the court of appeals' failure to perceive "*a single cogent reason*" (Pet. App. 62a) for Congress's decision sometimes to deprive first applicants of exclusivity when a patent is delisted. To be sure, consumers benefit from the accelerated arrival of generic competition that is encouraged by the promise of exclusivity. But as the foregoing discussion illustrates, consumers also benefit from the entry of multiple generic competitors, something that exclusivity delays.

The trade-offs between those two objectives are potentially complex, and the MMA reflects Congress's nuanced judgment—based on two decades of experience since the passage of the Hatch-Waxman Amendments—about how best to serve consumer welfare in the generic drug market. Under these circumstances, the best guide to Congress's intent is the terms of the statute itself, not a perception of some overarching, implicit statutory "incentive structure."

5. Although FDA's interpretation of the statute is rooted in the plain language of the statutory text, the agency also stated that, even if the statute is considered ambiguous, it would have reached the same outcome. Pet. App. 26a. It is arguable that the silence of the forfeiture provisions respecting the precise circumstance presented in this case "creates ambiguity," rather than "resolve[s] it." *Barnhart* v. *Walton*, 535 U.S. 212, 218 (2002). Thus, to the extent that the statute is ambiguous, the court of appeals compounded its error in *Teva* by failing to defer to the agency's reasonable interpretation, as required by *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 843-844 (1984).

B. Despite the fundamental errors in the court of appeals' decision below and in *Teva*, this Court's review is not warranted at this time. As the discussion above suggests, inappropriately awarded periods of generic exclusivity have substantial adverse effects on consumer welfare, principally in the form of delayed realization of the benefits of full generic competition. But because Teva's periods of exclusivity here have ended, those losses to actual or potential losartan consumers are irretrievable. Much the same is likely to be true of any particular case in the future that reaches this Court. FDA generally does not determine whether any ANDA appli-

cant is entitled to exclusivity until final approval of the first ANDA, see Pet. App. 16a n.6, so future litigation over exclusivity issues is not likely to be finally resolved by this Court before the 180-day period of exclusivity expires.[3]

Thus, the pertinent questions are (1) whether exclusivity litigation can be expected to arise in the future with sufficient frequency to warrant this Court's immediate correction of the court of appeals' error, and (2) whether the decision below and *Teva* sufficiently frame and explore the range of interrelated exclusivity issues the Court might need to address. On both counts, the Court may benefit from deferring review.

With respect to the frequency of future litigation, FDA has had only four occasions to consider the issues raised here since the MMA's enactment. The certiorari petition argues that future litigation in this area is indeed possible: "there are 27 patents for brand-name drugs—including several blockbusters—for which ANDAs including paragraph IV certifications have been filed and the challenged patent has been delisted or allowed to expire." Pet. 25. It is difficult to speculate

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[3] The government agrees with petitioner (see Pet. 17 n.8) that the question presented is "capable of repetition, yet evading review," and thus falls within that well established exception to the mootness doctrine. See *Davis* v. *FEC*, 554 U.S. 724, 735 (2008) (quoting *FEC* v. *Wisconsin Right to Life, Inc.* (*WRTL*), 551 U.S. 449, 462 (2007)). In particular, as discussed in the text, "the challenged action is in its duration too short to be fully litigated prior to * * * expiration." *Ibid.* And although FDA does not disclose who is and is not a first ANDA applicant, see 21 C.F.R. 314.430(b), it is reasonable to assume based on petitioner's past business activities that it will in the future be a subsequent ANDA applicant, thus raising "a reasonable expectation that the same complaining party will be subject to the same action again." *Davis*, 554 U.S. at 735 (quoting *WRTL*, 551 U.S. at 462).

whether any of those ANDAs may generate an actual controversy over forfeiture of exclusivity, or what form that controversy might take. That uncertainty, and the historically small volume of exclusivity forfeiture controversies, suggest that the Court may benefit from waiting to see how often such controversies materialize.

That approach should also allow for percolation of the substantive legal issues. Petitioner acknowledges (Pet. 28) there is no split in the circuits on the question presented. But one could evolve. Should a new exclusivity forfeiture controversy materialize, it is reasonable to assume that FDA would, as here, follow the reasoning of *Teva*. Indeed, the agency may have little choice as a practical matter, because any challenge to FDA's action may be brought against the Secretary of Health and Human Services in the District of Columbia, and the D.C. Circuit constrained FDA's interpretation of the statute by rendering its structure-based interpretation of the MMA amendments at "*Chevron* step one," Pet. App. 64a. In those circumstances, as here, the subsequent ANDA applicant advocating forfeiture would be a proper plaintiff. Alternatively, a party with a bona fide stake in the outcome could invoke FDA's "citizen petition" procedure, see 21 C.F.R. 10.30, and challenge the agency's decision in an appropriate court. Given the D.C. Circuit's unfavorable precedent, the subsequent applicant or citizen petitioner would presumably file elsewhere—such a challenge could be filed in a district where either FDA, the subsequent applicant, or the citizen petitioner resides, see 28 U.S.C. 1391(e). Thus, if the question presented is of recurring importance, it will likely be next presented to another court of appeals.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

NEAL KUMAR KATYAL
Acting Solicitor General

TONY WEST
Assistant Attorney General

DOUGLAS N. LETTER
CHRISTINE N. KOHL
Attorneys

DECEMBER 2010

Nos. 10-453

IN THE

Supreme Court of the United States

APOTEX, INC.,

Petitioner,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, *ET AL.*,

Respondents.

On Petition for Writ of Certiorari to the U.S. Court of Appeals for the D.C. Circuit

BRIEF IN OPPOSITION OF RESPONDENT TEVA PHARMACEUTICALS USA, INC.

JAY P. LEFKOWITZ, P.C.
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, NY 10022
(212) 446-4800
jay.lefkowitz@kirkland.com

MICHAEL D. SHUMSKY
Counsel of Record
AARON L. NIELSON
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
mshumsky@kirkland.com
anielson@kirkland.com

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WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether the D.C. Circuit erred in holding that the district court did not abuse its discretion by denying Petitioner's motion for preliminary injunctive relief.

PARTIES TO THE PROCEEDING

Petitioner Apotex, Inc. was the plaintiff-appellant below.

Respondents Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services; Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs; the U.S. Food and Drug Administration; and the U.S. Department of Health and Human Services were the defendants-appellees below.

Respondent Teva Pharmaceuticals USA, Inc. was an intervenor-defendant/appellee below.

Non-party Roxane Laboratories, Inc. was a plaintiff-appellant below and thus is a respondent under this Court's Rule 12.6.

CORPORATE DISCLOSURE STATEMENT

Respondent Teva Pharmaceuticals USA, Inc. ("Teva") is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. through the following parent companies: (i) Orvet UK Unlimited (Majority Shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd.; and (ii) Teva Pharmaceutical Holdings Cooperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva. Teva Pharmaceutical Industries Ltd. is the only publicly traded direct or indirect parent company of Teva, and no other publicly-traded company owns more than 10% of its stock.

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INTRODUCTION

Respondent Teva Pharmaceuticals USA, Inc. ("Teva") began selling generic losartan potassium products on the evening of April 6, and its 180-day period of marketing exclusivity for those products thus ended at the stroke of midnight on October 3—the day *before* Apotex, Inc. ("Apotex") filed its Petition challenging Teva's then-expired exclusivity period. Accordingly, this case was moot on arrival, and the Petition should be denied. Nothing this Court can say or do would revive Apotex's lone claim, which sought only declaratory and injunctive relief that would have allowed the company to launch its losartan potassium products *before* the scheduled expiration of Teva's now-concluded exclusivity period. Needless to say, this Court is not in the business of exercising its discretionary jurisdiction to render advisory opinions on purely academic matters, and it should not do so here.

This case would in any event be a spectacularly poor vehicle for doing so, because it bears the dubious distinction of attempting to raise a *moot* question in an *interlocutory* posture. After all, no final judgment has been entered below. The district court merely denied Apotex's motion to preliminarily enjoin Teva from marketing its products, and the D.C. Circuit's opinion simply affirmed that discretionary decision before remanding the case. Pet. App. 3a.

While Apotex nonetheless pretends that the merits of its claim are before the Court, *see* Pet. at i, that simply isn't so. The preliminary injunction calculus turns not only on whether the movant has shown a likelihood of success, but also requires proof

that the movant is "likely" to suffer irreparable harm in the absence of interim relief. *Winter v. NRDC, Inc.*, 129 S.Ct. 365, 375-76 (2008). Apotex, however, does not challenge the district court's factual finding that it would not have suffered an irreparable harm from the denial of injunctive relief—and, given that Teva's exclusivity period has come and gone, Apotex cannot possibly make that showing now. There is thus no basis for reaching the merits. The D.C. Circuit's decision to affirm the district court's denial of Apotex's preliminary injunction motion could be summarily affirmed based solely on the equities, leaving any discussion of the merits for an appeal in which the legal issues are presented squarely (and actually matter).

And while the fact that Apotex's requests for preliminary and permanent injunctive relief *both* are moot seemingly would leave the district court with little left to do on remand, Apotex apparently doesn't think so. When the district court recently issued an order to show cause why judgment should not be entered in favor of FDA (and Teva), Apotex opposed the entry of final judgment; indeed, it would not even commit to dismissing its lawsuit in the event this Court denies *certiorari*. Resp. App. 8a.

Even if there were no jurisdictional or procedural impediment to this Court's review, and even if the merits were squarely presented, there still would be no need for the Court to intervene. In short, there is no division of authority on the single question presented by the Petition. Two different panels of the D.C. Circuit now have rejected Apotex's arguments, in decisions that are fully consistent with that of a third D.C. Circuit panel that rejected

Apotex's arguments under the prior version of the statute, *see Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). Suffice it to say, no other court has weighed in on the other side (whether under this version of the statute or its predecessor).

Apotex tries to downplay the courts' consistent rejection of its arguments by speculating that a circuit split is unlikely to develop because most Hatch-Waxman cases are filed in the District of Columbia. But there is no reason why that must be so: Unlike many federal agencies whose decisions are subject to exclusive review in the D.C. Circuit, FDA can be—and often is—sued in other jurisdictions. That likely explains why the Agency's senior Hatch-Waxman counsel reportedly told a recent conference that the issues implicated by this litigation are "likely to arise again soon *in other courts*." David Belian, *FDA Expects More Litigation Over Generic Exclusivity*, GENERIC LINE, Oct. 27, 2010 (Resp. App. 11a) (emphasis added).

Finally, and perhaps most important, the D.C. Circuit's analysis was correct. Contrary to Apotex's assertion that the appellate court "gave no meaningful consideration to th[e statute's] text," Pet. 29, that's precisely what the D.C. Circuit did. In fact, Apotex's real complaint is not that the D.C. Circuit failed to consider the statutory text; it is that the appellate court considered *the whole text* of the statute and not just the snippets Apotex focuses on. Indeed, as Judge Williams carefully explained in the precursor to the decision at issue here, Apotex's proposed interpretation of the statute's forfeiture triggers is both inconsistent with the remainder of the statute's text and structure and unsupported by

even "*a single cogent reason.*" Pet. App. 62a (emphasis in original).

In sum, *certiorari* is unwarranted by any measure. This case is both moot and interlocutory; there is no circuit split; and the decision below is plainly correct. The Petition should be denied.

OPINIONS BELOW

The D.C. Circuit's unreported *per curiam* disposition is reprinted at Pet. App. 1a-3a. The district court's opinion is reported at 700 F. Supp. 2d 138 (D.D.C. 2010) and reprinted at Pet. App. 4a-11a. The Food and Drug Administration's unreported Letter Decision is reprinted at Pet. App. 12a-30a.

Neither FDA nor Apotex timely petitioned this Court for review of the D.C. Circuit's related decision in *Teva Pharmaceuticals USA, Inc. v. Sebelius*, which is reported at 595 F.3d 1303 (2010). Nonetheless, much of Apotex's Petition addresses the merits of that decision, which is reprinted at Pet. App. 31a-71a. The underlying district court decision in that case is reported at 638 F. Supp. 2d 42 (D.D.C. 2009) and reprinted at Pet. App. 72a-106a.

JURISDICTION

The D.C. Circuit's judgment was entered on July 6, 2010, and Petitioner has invoked this Court's jurisdiction under 28 U.S.C. § 1354(1). As set forth below, however, the Petition does not present a live case or controversy, and this Court accordingly lacks Article III jurisdiction to reach the merits. *See* U.S. CONST. art. III.

PERTINENT STATUTORY AND CONSTITUTIONAL PROVISIONS

Petitioner's Appendix includes some—but not all—of the pertinent statutory provisions. The remainder are set forth at Resp. App. 1a-6a.

STATEMENT OF THE CASE

A. The Hatch-Waxman Framework

As modified by the Medicare Modernization Act ("MMA"), the Hatch-Waxman Act establishes the procedure for obtaining new drug approvals in the United States. 21 U.S.C. § 355 *et seq.* It requires the manufacturer of a proposed brand-name drug to complete a New Drug Application ("NDA") that contains clinical data showing the proposed drug's safety and efficacy, *id.* § 355(b)(1), as well as information regarding each patent the applicant asserts as claiming the proposed drug (including its scheduled expiration date), *id.* § 355(b)(2); 21 C.F.R. § 314.50(h); *id.* § 314.53(b).

Generic drugs contain the same active ingredients and provide the same benefits as their brand-name counterparts, but typically are less expensive. Before Hatch-Waxman, generic companies had to complete a full NDA to obtain FDA approval; that requirement almost invariably made generic market entry cost-prohibitive. In 1984, Congress enacted Hatch-Waxman to remove that barrier, increase the availability of generics, and reduce drug costs. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

To that end, Hatch-Waxman authorizes FDA to approve a generic drug if the generic applicant can

demonstrate its product's bioequivalence to a "listed" (or previously approved) brand-name drug. Generic applicants do so by submitting an Abbreviated NDA ("ANDA") that includes studies demonstrating bioequivalence. 21 U.S.C. § 355(j). If FDA accepts those studies, the generic applicant need not replicate the brand manufacturer's clinical studies. *Id.* § 355(j)(2)(A); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

The statute also requires each ANDA to include a "certification" to each patent the brand manufacturer identified as claiming the brand-name drug. *Id.* § 355(j)(2)(A)(vii). To make this system work, FDA must "publish" the patent information it receives from brand companies. *Id.* § 355(j)(7)(A). FDA's official patent list is known as "the Orange Book." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004).

Generic applicants consult that list and then make one of four certifications: (1) that no patent information was filed for the brand-name drug ("Paragraph I certification"); (2) that a listed patent "has expired" ("Paragraph II certification"); (3) that the generic drug will not be marketed until "the date on which [a listed] patent will expire" ("Paragraph III certification"); or (4) that a listed patent is invalid, unenforceable, and/or will not be infringed by the proposed generic drug ("Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

Paragraph IV certifications are critically important. They typically signal the generic's intent to sell its products before the scheduled expiration of a listed patent and thereby provide consumers with expedited price relief. *Teva Pharms. USA, Inc. v.*

Leavitt ("*Teva v. Leavitt*"), 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier.").

But filing such certifications is risky. The first Paragraph IV challenger bears significant research-and-development and legal costs to design around and/or contest the validity of a listed patent. And if those efforts succeed, merely filing such a certification is an act of infringement that could result in years of costly patent litigation. *See* 35 U.S.C. § 271(e); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

To encourage generics to accept those risks, the statute rewards the first patent challenger with a 180-day period of marketing exclusivity during which no other generic version of the drug may be sold. *See, e.g.*, *Teva v. Leavitt*, 548 F.3d at 104 ("Marketing exclusivity is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation.").

Pursuant to the MMA, the first patent challenger can "forfeit" its exclusivity in certain circumstances. 21 U.S.C. § 355(j)(5)(D)(i). Two such circumstances are relevant here. First, the first generic applicant can forfeit exclusivity if it fails promptly to market its products after certain events—including (in general terms) a successful outcome in patent litigation, or after the brand manufacturer withdraws (or "delists") a patent from the Orange Book. *Id.* § 355(j)(5)(D)(i)(I). These provisions are known as the "failure-to-market" forfeiture trigger.

Second, the first applicant may forfeit exclusivity if "[a]ll of the patents as to which the applicant submitted a [Paragraph IV certification] have expired." *Id.* § 355(j)(5)(D)(i)(VI). This provision codified FDA's longstanding practice of rejecting exclusivity where the first applicant failed to begin selling its products before the challenged patent expired *naturally—i.e.*, at the end of its scheduled term. *See Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354-55 (D.N.J. 2003).

B. The Delisting Rule

Shortly after Congress passed Hatch-Waxman, brand companies realized that delisting a challenged patent could eliminate exclusivity and thereby undercut the incentive for generic applicants to challenge patents over the long-run. That was so because generic applicants can certify *only* to patents listed in the Orange Book, and can receive exclusivity *only* if they maintain a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv) (2002); *id.* § 355(j)(5)(B)(iv)(II)(bb) (2003). FDA acquiesced in this practice, and given the ease with which brand manufacturers thus could eviscerate the incentive for challenging their patents, FDA's approach to delisting substantially reduced the motivation for generic applicants to develop and file early patent challenges.

Teva eventually sued FDA, and the D.C. Circuit rejected the Agency's acquiescence in this manipulative practice at *Chevron* step one. *Ranbaxy*, 469 F.3d at 126. As *Ranbaxy* explained, FDA's delisting policy gutted the exclusivity reward by allowing brand companies to "reduce[] the certainty of receiving a period of marketing

exclusivity," and thereby "diminish[ed] the incentive for [generics] . . . to challenge a [listed] patent." *Id.* at 126. In sum, the Court held, "FDA may not . . . change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'" *Id.* (quoting *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994)).

Ranbaxy, however, was decided before the MMA. And seizing upon the MMA's new "failure-to-market" forfeiture clause—which in certain circumstances provides for forfeiture after a delisting, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)—FDA held that *Ranbaxy* did not survive the MMA. Pet. App. 36a. Instead, according to FDA, "[b]rand manufacturers are ... free to delist challenged patents *whenever* they please—and any such delisting [causes a forfeiture]." *Id.* at 58a (emphasis added). This approach was known as the "Delisting Rule."

C. Losartan Potassium Products

Losartan potassium is an antihypertensive agent. Merck holds two NDAs for the losartan potassium products Cozaar® and Hyzaar®. When those drugs were approved, Merck listed the same three patents[1] in the Orange Book for both: U.S. Patent No. 5,138,069 ("the '069 patent"), which was scheduled to block competition through February 11, 2010; U.S.

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[1] Merck also listed a fourth patent for Cozaar®, but that patent relates to a treatment for which Teva did not seek approval and thus posed no barrier to the approval of Teva's ANDA.

Patent No. 5,153,197 ("the '197 patent"), which was scheduled to block competition through April 6, 2010; and U.S. Patent No. 5,608,075 ("the '075 patent"), which was scheduled to block competition through September 4, 2014.[2]

On December 18, 2003, Teva submitted its generic Cozaar® ANDA. Teva's ANDA contained Paragraph III certifications to the '069 and '197 patents, meaning that it would not market its products until the '197 patent's scheduled expiration in April 2010. However, Teva also submitted a Paragraph IV certification to the '075 patent, claiming that that patent is invalid, unenforceable, and/or would not be infringed by Teva's products—and thus that Teva intended to begin marketing its products years before that patent's scheduled expiration in 2014. Teva was the first generic applicant to challenge the '075 patent. Pet. App. 40a.

On May 24, 2004, Teva submitted its generic Hyzaar® ANDA. That ANDA contained the same patent certifications as Teva's Cozaar® ANDA—including a Paragraph IV certification to the '075 patent. Once again, Teva was the first generic Hyzaar® applicant to challenge the '075 patent. *Id.*

As the first Paragraph IV filer, Teva became eligible for 180-day exclusivity for both drugs. *Id.* Teva then notified Merck of its certifications, explaining that most of the '075 patent's claims were

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[2] Each patent actually was scheduled to expire before these dates. However, Merck received a period of "pediatric exclusivity" which prevented FDA from approving ANDAs until six months after each patent expired. 21 U.S.C. § 355a.

invalid based on prior art and that Teva's products would not infringe the patent's remaining claims under the doctrine of equivalents. Merck, however, did not sue Teva. *Id.* Instead, in March 2005—*after* Teva submitted its exclusivity-qualifying Paragraph IV certifications to the '075 patent—"Merck asked the FDA to delist the '075 patent, which the agency did." *Id.* Then, *after* asking FDA to delist the '075 patent, Merck apparently stopped paying "maintenance fees" on the now-worthless patent. *Id.* at 6a.

By doing so, Merck effectively conceded that Teva's Paragraph IV challenge was so strong that Merck could not reasonably assert that patent against any generic applicant. Teva thus achieved precisely what Congress sought to reward with exclusivity: It identified a competition-blocking patent, invested the resources needed to challenge it, and successfully removed it as a barrier to competition—thereby opening the market to generic entry more than four years earlier than would have been possible without Teva's challenge. Under FDA's Delisting Rule, however, "Teva had by the fall of 2008 *already* forfeited" its exclusivity because of Merck's unilateral decision to delist the '075 patent. *Id.* at 41a (emphasis original).

D. The *Teva* Litigation

In June 2009, Teva sued FDA to protect its 180-day exclusivity period, arguing that the Delisting Rule was arbitrary, capricious, and inconsistent with the statute. The district court (Collyer, J.) ultimately consolidated Teva's initial request for preliminary injunctive relief with a trial on the merits, and entered judgment for FDA. *Id.* at 33a.

Teva appealed, and the D.C. Circuit (per Williams, J.) reversed on March 2, 2010. *Id.* at 66a. Paying close attention to the statute's text and structure, Judge Williams's opinion for the court held there was "no reason to conclude that the 2003 addition of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity." *Id.* at 63a; *see also id.* at 62a ("The agency ... *offers not a single cogent reason* why Congress might have ... provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity.") (emphasis original).

The D.C. Circuit then remanded the case for the entry of appropriate relief, *id.* at 66a, but simultaneously entered a routine order withholding its mandate until seven days after FDA's deadline for seeking rehearing.

E. Post-Judgment Proceedings

That routine order would have prevented the district court from entering relief on remand *before* FDA could have approved other applicants on April 6. So on March 9, Teva moved the D.C. Circuit to issue its mandate forthwith. Emer. Mot. To Issue Mandate (Mar. 9, 2010).

That same day, however, Apotex apparently informed FDA that Merck's '075 patent may have prematurely expired *in March 2009* due to Merck's unilateral failure to pay maintenance fees. FDA then opposed Teva's motion for immediate issuance of the mandate, asserting (like Apotex here) that Merck's decision to halt maintenance fee payments meant that "a forfeiture event other than the delisting of the '075 patent—namely, expiration of a patent that is the subject of a paragraph IV

certification[—]has, in fact, occurred." FDA Opp. to Emer. Mot. To Issue Mandate at 7 (Mar. 11, 2010).

Teva promptly replied, explaining that FDA's effort to divorce Merck's unlawful delisting request from its failure to pay maintenance fees

> boils down to the absurd proposition that brand manufacturers somehow are allowed to achieve through the back door (by not paying maintenance fees on a challenged patent) precisely what th[e D.C. Circuit]'s decisions in both this case and *Ranbaxy* forbid them from doing through the front door (by delisting the challenged patent in the first place). As [*Teva*] recognized, however, there is 'not a single cogent reason why Congress might have permitted ... a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity,' and that judgment is controlling here.

Reply in Supp. of Emer. Mot. at 11 (Mar. 12, 2010) (quoting Pet. App. 62a). After considering the parties' submissions, the D.C. Circuit granted Teva's motion and issued its mandate on March 12.[3]

F. Post-Remand Proceedings

On remand, the district court directed FDA to promptly file an administrative decision addressing the potential impact of Merck's conduct on Teva's eligibility for exclusivity, and suggested that any challenge to that decision could be raised "in a new

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[3] FDA later petitioned for rehearing *en banc*, but the D.C. Circuit unanimously denied the petition on May 17.

lawsuit." Order Amending Judgment at 3 n.4 (D.D.C. Mar. 26, 2010).

On March 26, FDA then issued the Letter Decision giving rise to this litigation. Pet. App. 12a-30a. Although the Agency took issue with the D.C. Circuit's delisting opinion, it nonetheless held that the appellate court's reasoning "preclude[s] a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder." *Id.* at 28a (discussing *id.* at 62a). It therefore declared that FDA "will not approve any other [losartan] ANDA until [Teva] has received approval of its ANDA, begun commercial marketing, and the 180-day exclusivity period has expired." *Id.* at 29a.

Apotex then filed a new lawsuit, seeking a TRO and preliminary injunction that together would bar FDA from awarding Teva exclusivity and compel the Agency to approve Apotex's ANDA immediately. On April 2, the district court denied the motion. *Id.* at 11a. With respect to Apotex's likelihood of success, the district court held that FDA properly "applied the reasoning of the Circuit to a different but, on these facts, closely related question." *Id.* at 9a. And on the equities, the court held that Apotex's purely economic injuries did not constitute irreparable harm, *id.* at 10a; that the requested relief "would certainly injure Teva," *id.*; and that the public interest weighed against relief given the exclusivity reward's "'pro-consumer'" goals. *Id.* at 10a-11a (quoting *id.* at 64a).

On April 5, Apotex asked the D.C. Circuit to stay all generic losartan approvals and summarily reverse the district court's decision. The D.C. Circuit

promptly denied those motions, and FDA approved Teva's ANDAs on April 6. Teva began selling its products that evening, thereby triggering its 180-day exclusivity period.

On July 6, another D.C. Circuit panel (Tatel, Griffith, Kavanaugh, JJ.) affirmed the district court's denial of Apotex's preliminary injunction request in an unpublished *per curiam* order. Pet. App. 1a-3a. That summary disposition explained that once "the Hatch-Waxman Act's forfeiture provisions are viewed in the context of the statute's incentive structure, it becomes clear that Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent ... to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute." *Id.* at 2a-3a.

Teva's 180-day period of exclusivity ended on October 3. The next day, Apotex filed its Petition. Apotex received approval to market its generic losartan potassium products on October 6, and apparently has been selling its products ever since.[4]

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[4] *See* FDA, *Drugs @ FDA: FDA Approved Drug Products*, *at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=090790&DrugName=LOSARTAN%20POTASSIUM&ActiveIngred=LOSARTAN%20POTASSIUM&SponsorApplicant=APOTEX%20CORP&ProductMktStatus=1 (last visited Dec. 9, 2010).

REASONS FOR DENYING THE WRIT

I. This Case Is Moot.

Apotex's complaint—and the preliminary injunction motion addressed by the sole D.C. Circuit decision at issue here, Pet. App. 2a-3a—sought only prospective relief challenging Teva's entitlement to 180-day marketing exclusivity. But Teva's 180 days of exclusivity have come and gone, and while this Court can do many things, it can't turn back time. There is thus no case or controversy left for the Court to resolve; any opinion regarding the merits would be purely advisory.

Nor does this case present one of those "exceptional situations" involving an issue that is "capable of repetition while evading review." *Alvarez v. Smith*, 130 S. Ct. 576, 581 (2009) (internal citations and quotations omitted). Though Apotex has identified a handful exclusivity-grounding patents that the brand manufacturer deliberately let lapse, there is no reason why the question it seeks to raise here will evade review if, as Apotex speculates, it ever arises again. After all, challenges to the legal rules FDA applies in making exclusivity decisions can be brought well before an exclusivity period is scheduled to begin—and with ample time for this Court to review the issue Apotex seeks to raise in a case where it actually matters.

A. This Case Was Moot Even Before Apotex Filed Its Petition.

It is black-letter law that "a case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Powell v. McCormack*, 395 U.S. 486, 496 (1969).

Accordingly, a given case or controversy not only must be "live" at the outset of litigation; it must remain so "'through all stages of federal judicial proceedings, trial and appellate.'" *Spencer v. Kemna*, 523 U.S. 1, 7 (1998) (quoting *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477-478 (1990)).

Apotex's lawsuit, however, was moot even before the Petition was filed. This case involved a single 180-day period of marketing exclusivity that began on April 6 and ended at midnight on October 3. Apotex is now selling its products, unhindered by the exclusivity period it sought to challenge. Any interest Apotex had when it filed suit long ago ceased to exist; nothing this Court can do would give Apotex relief. Accordingly, the Petition should be denied. *See Lewis*, 494 U.S. at 480 ("Where on the face of the record it appears that the only concrete interest in the controversy has terminated, reasonable caution is needed to be sure that mooted litigation is not pressed forward, and unnecessary judicial pronouncements ... obtained."); *see also Bunting v. Mellen*, 541 U.S. 1019, 1021 (2004) (Stevens, Breyer, and Ginsburg, JJ., respecting the denial of certiorari) (explaining that *certiorari* is properly denied where "there no longer is a live controversy").

B. This Issue Will Not Evade Review.

Nonetheless, Apotex half-heartedly suggests that this case falls within the "capable of repetition, yet evading review" exception to mootness. *See* Pet. 17 n.8. But that bald assertion is incorrect: There is no reason to assume that future cases raising this issue cannot be filed with "ample time to obtain judicial review." *Lewis*, 494 U.S. at 482.

That is so, as the D.C. Circuit's original delisting decision made clear, because there is no bar to pre-enforcement review of exclusivity issues. Given that the issues presented in such cases are "purely legal" and implicate a cognizable "hardship," Pet. App. 43a, 46a, courts "routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." *Id.* at 48a (citations omitted).

That, of course, explains why Apotex does not even try to argue that subsequent cases cannot be filed with sufficient lead-time to permit full judicial review. All a subsequent applicant would have to do is file a declaratory judgment action next time it faces an allegedly unlawful exclusivity period—and if Apotex is to be believed, there are 27 possible cases in which one might do so, *see* Pet. 25 (though that considerably overstates the number of cases in which the actual merits issue embedded in this preliminary injunction appeal might arise, *see infra* at III.B.).

In any event, this Court need "not decide in the first instance" whether an exception to the mootness doctrine applies. *Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 168-169 (2004) (internal citation and quotations omitted). As explained below, this case remains pending before the district court—which can and should resolve the mootness issue (by making any necessary findings that bear on that inquiry) in the first instance. *See, e.g., United States v. Brandau*, 578 F.3d 1064, 1065 (9th Cir. 2009); *Pakootas v. Teck Cominco Metals, Ltd.*, 452 F.3d 1066, 1071 n.10 (9th Cir. 2006); *Tandy v. City of Wichita*, 380 F.3d 1277, 1291 (10th Cir. 2004).

II. The Petition Arises In The Interlocutory Context Of A Preliminary Injunction Proceeding.

Even if this case were not moot, it would be a poor vehicle to address the question it purports to present, because it arises in the interlocutory context of a preliminary injunction proceeding. Again, the D.C. Circuit merely affirmed the district court's denial of Apotex's motion for interim relief, and the case remains pending below.

This Court typically does not exercise its discretionary jurisdiction over interlocutory appeals, and petitions arising from preliminary injunction proceedings are particularly ill-suited for review. After all, the legal issues embedded in such petitions are not squarely presented: The question on appeal from the denial of a preliminary injunction is *not* whether the lower courts properly resolved the merits, but whether the court abused its discretion by denying interim relief. While that inquiry turns in part on a tentative assessment of the merits, it also requires the movant to demonstrate a likelihood of irreparable injury absent immediate relief. Here, of course, Apotex cannot possibly demonstrate such an injury because Teva's exclusivity period is over—and the D.C. Circuit's decision thus would have to be affirmed without respect to the merits.

A. There Has Been No Final Judgment.

As set forth above, no final judgment has been entered in this case. That fact alone is fatal to the Petition, because this Court's settled practice is to "await final judgment in the lower courts before exercising ... certiorari jurisdiction." *VMI v. United States*, 508 U.S. 946, 946 (1993) (Scalia, J.,

respecting the denial of certiorari) (citing *American Constr. Co. v. Jacksonville, T. & K.W.R. Co.*, 148 U.S. 372, 384 (1893); *Locomotive Firemen v. Bangor & Aroostook R. Co.*, 389 U.S. 327, 328 (1967) (per curiam); R. Stern, E. Gressman, & S. Shapiro, SUPREME COURT PRACTICE § 4.18, pp. 224-226 (6th ed. 1986)).

That approach controls here, where the *only* decision before this Court is the D.C. Circuit's unpublished order affirming the district court's denial of Apotex's preliminary injunction motion. Pet. App. 2a-3a. The legal merits remain pending before the district court on remand. And while one might think there is little left for the district court to resolve given that Teva's exclusivity period now has ended, Apotex continues to resist the entry of a final judgment; indeed, Apotex won't even commit to dismissing its lawsuit in the event this Court denies *certiorari*. *See* Resp. App. 8a ("Should the petition not be granted, Apotex will then *consider* whether to dismiss the case ....") (emphasis added).

The Petition thus should be denied. While Teva has no idea what Apotex intends to do at the district court, this Court's review can surely await the entry of judgment after Apotex decides it has finished litigating the merits of its case.

B. The Legal Issue Apotex Seeks To Raise Is Not Squarely Presented.

The fact that this Petition arises from the denial of a preliminary injunction provides an additional basis for denying review. While Apotex purports to raise the purely legal question of whether the D.C. Circuit properly interpreted the Hatch-Waxman Act, *see* Pet. i, that question isn't actually presented.

Instead, the only question before this Court is whether the district court abused its discretion when it applied the four-factor preliminary injunction test to deny Apotex's motion. *See Winter*, 129 S. Ct. at 374; *Munaf v. Geren*, 553 U.S. 674, 690-91 (2008).

Yet for all the ink it spills on the underlying merits, Apotex doesn't say a word about the preliminary injunction standard—and for good reason. As the district court recognized, Pet. App. 8a-9a, that standard requires Apotex to demonstrate, among other things, both a likelihood of success on the merits *and* a likelihood of irreparable injury in the absence of immediate equitable relief. *Winter*, 129 S. Ct. at 374-75.

Apotex cannot satisfy either requirement. On one hand, the fact that Apotex's sole legal claim is moot forecloses any possibility that Apotex could demonstrate a likelihood of success. On the other hand, Apotex does not contest the district court's factual finding that the company would not suffer irreparable injury absent injunctive relief. Pet. App. 10a (citing *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam); *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001)). And Apotex certainly cannot demonstrate such an injury now: Teva's exclusivity period is over, and Apotex is on the market. There is thus nothing left to enjoin, and no need for this Court to reach the merits. The case would have to be affirmed based solely on the equities. *See, e.g.*, *Winter*, 129 S. Ct. at 374-76 (conditioning injunctive relief on proof that irreparable injury is "likely," and denying such relief without addressing the merits

based on "[a] proper consideration of the[equitable] factors *alone*") (emphasis added).

III. There Is No Circuit Split, And Apotex Exaggerates the Likelihood That The Embedded Merits Issue Will Recur.

Separate and apart from those grounds for denying the Petition, there is no circuit split on the issue Apotex purports to raise, and Apotex in any event exaggerates the likelihood that it will recur.

A. There Is No Circuit Split.

Apotex concedes that the D.C. Circuit is the only appellate court that has addressed whether the Hatch-Waxman Act allows brand manufacturers to deprive generic applicants of 180-day exclusivity by ceasing to pay maintenance fees on Orange Book-listed patents. Pet. 26. And the appellate court's decision on this point is both fully consistent with two prior D.C. Circuit cases, *see* Pet. App. 31a-71a; *Ranbaxy*, 469 F.3d at 126, and uncontested by any other circuit court.

Despite this uniformity, Apotex claims that *certiorari* is appropriate because it believes a circuit split is unlikely to develop. *See* Pet. 26-27. That is so, Apotex asserts, because "the D.C. Circuit is the usual forum for these disputes." *Id.* at 26 (internal quotation omitted).

Unlike many federal agencies, however, FDA is not subject to exclusive suit in the D.C. Circuit. And despite Apotex's best efforts to obscure the record, lawsuits regarding FDA's interpretation of the Hatch-Waxman Act (including its 180-day exclusivity provisions) commonly *are* filed outside Washington D.C. Indeed, these out-of-circuit cases include some

of the most significant Hatch-Waxman cases that have ever been litigated. *See, e.g.*, *Mylan Pharms., Inc. v. FDA*, 454 F.3d 270 (4th Cir. 2006) (180-day exclusivity); *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003) (Orange Book patent listings); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (same); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (Orange Book patent listings); *Granutec, Inc. v. Shalala*, Nos. 97-1873, 97-1874, 1998 WL 153410 (4th Cir. Apr. 3, 1998) (180-day exclusivity); *Schering Corp. v. FDA*, 51 F.3d 390 (3d Cir. 1995) (generic approval requirements); *Dr. Reddy's Labs.*, 302 F. Supp. 2d at 340 (180-day exclusivity); *Mylan Pharms., Inc. v. Thompson*, 207 F. Supp. 2d 476 (N.D. W.Va. 2001) (180-day exclusivity).

That perhaps explains why FDA itself is preparing to litigate these issues in other jurisdictions. Indeed, as the Agency's senior Hatch-Waxman counsel recently explained, FDA expects that the issues addressed in the losartan cases are "likely to arise again soon *in other courts*." Resp. App. 11a (emphasis added). There is thus no basis for Apotex's attempt to rule out the possibility of a future circuit split.

Faced with these facts, Apotex ultimately resorts to speculation. It hypothesizes that future first applicants might be able to channel all 180-day exclusivity cases to the D.C. courts before subsequent applicants are "able to bring suit elsewhere." Pet. 27. But without belaboring the point, such admittedly creative conjecture—which even Apotex concedes rests on an "unclear" premise, *id.*—hardly provides a basis for granting *certiorari*.

B. Apotex Exaggerates The Likelihood That The Embedded Merits Issue Will Recur.

Of course, the absence of a circuit split does not automatically preclude review; this Court sometimes takes cases that present particularly important issues which are likely to recur. Apotex thus tries to shoehorn its Petition into this narrow class of cases, asserting that "billions of dollars" are at stake because "[m]any more [cases] are coming down the pike." Pet. 24-25. Indeed, Apotex argues, it has identified "27 patents for brand-name drugs ... for which ... the challenged patent has been delisted *or* allowed to expire." *Id.* at 25 (emphasis added).

That not only overstates the case; it highlights yet another problem with the Petition. Despite Apotex's best efforts to challenge the D.C. Circuit's original delisting decision (Pet. App. 31a-71a), this Petition does *not* arise from Teva's lawsuit challenging the FDA's Delisting Rule, and the decision in that case is *not* before the Court. Instead, this case arises from Apotex's subsequent—*separate*—lawsuit challenging FDA's application of the patent-expiry forfeiture trigger, and that's the only merits issue addressed in the appellate court's preliminary injunction decision, Pet. App. 2a-3a.

That matters, because as Apotex noted in the district court (but tellingly declines to mention here), *only four* of the "27 patents" it claims to be at issue involve alleged patent expiry—*and one of those is the losartan patent at issue in this case.* *See* Apotex Reply to Opp. to Mot. for Prelim. Inj. at 8 & n.3 (D.D.C. Apr. 1, 2010). Thus, contrary to Apotex's suggestion that another 27 cases are likely to raise

the issue addressed by the appellate court, just 3 other cases implicate this issue—*and one of them appears to arise under the pre-MMA statute* (and so would not be controlled by a decision in this case). Neither of the remaining two cases involves a "blockbuster" drug, *cf.* Pet. 25, and even if they did, the prospect that two future cases may (or, depending on their unique facts, may not) give rise to similar litigation is far too thin a reed on which to ground *certiorari*.

IV. The D.C. Circuit's Preliminary Analysis Of The Merits Was Correct.

Finally, there is no need for this Court's review because the appellate court's preliminary analysis of the merits was correct. As three different panels of the D.C. Circuit now have recognized, it upends both law and logic to think that Congress created an elaborate incentive scheme designed to encourage generic companies to challenge dubious brand-name patents, but simultaneously empowered the brand companies who assert those dubious patents to eviscerate that incentive scheme. *Ranbaxy*, 469 F.3d at 126; Pet. App. 64a-66a; Pet. App. 2a-3a. In short, because Apotex's interpretation of the statute would allow brand companies to manipulate the exclusivity incentive despite the absence of *any* suggestion in the text, history, or structure of the statute that Congress intended to give brand companies that power, the D.C. Circuit properly held that Apotex was unlikely to prevail on the merits. Pet. App. 2a.

A. The MMA Did Not Abrogate *Ranbaxy*'s Holding On Delisting.

Long before this case arose, the D.C. Circuit held that the plain text and structure of the Hatch-

Waxman Act precluded FDA's policy of acquiescing in a brand manufacturer's unilateral request to delist a patent from the Orange Book following the submission of an exclusivity-qualifying Paragraph IV certification. As then-Chief Judge Ginsburg's opinion in *Ranbaxy* explained, "FDA's policy allows an NDA holder [to] diminish[] the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book.... FDA may not, however, change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'" *Ranbaxy*, 469 F.3d at 126 (quoting *MCI*, 512 U.S. at 231 n.4).

Apotex did not challenge that holding in either the original delisting case or its follow-on case regarding patent expiry. And apart from a stray footnote that would not be sufficient to raise the issue here even if it were not waived below, Pet. 26 n.11, Apotex does not seriously contest that holding now. Accordingly, as the D.C. Circuit recognized in its original delisting decision, "[t]he real issue" is whether the MMA "altered the statute's incentive structure to the point that *Ranbaxy*'s reasoning no longer controls ...." Pet. App. 60a.

Apotex contends that that's precisely what the MMA did, and points to the statute's new "forfeiture triggers" for support. Pet. 29-32. Indeed, Apotex claims that "[t]he D.C. Circuit gave no meaningful consideration to that text." *Id.* at 29; *see also id.* at 30 ("[T]he D.C. Circuit ... ignored those clear textual commands ...."). The court did no such thing.

To the contrary, its original delisting decision began by addressing the MMA's failure-to-market forfeiture trigger head-on—and carefully explained that the text of each of its subsections requires some action by the generic applicant before it kicks in:

> Setting aside the subsection at issue in this case—[the delisting forfeiture trigger] codified as (bb)(CC)—the "failure to market" forfeiture provision does not permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter. No forfeiture can take place unless the brand manufacturer brings an infringement suit against the generic and either loses on the merits or enters an unfavorable settlement agreement. The latter necessarily entails some participation by the generic; the former invariably involves significant expense for the brand manufacturer, and affords the victorious generic the opportunity to ask the court to delay entering final judgment until a date that would not trigger forfeiture prematurely.

Pet. App. 61a-62a (discussing 21 U.S.C. § 355(j)(5)(D)(i)(I)).

Apotex nonetheless claims that the delisting forfeiture trigger is different than the provisions to which it is connected: "The MMA specifically identified patent delisting as a 'forfeiture event' and gave no indication that it would not apply if that delisting was the result of 'unilateral' action by the brand-name manufacturer." Pet. 29. But the appellate court carefully considered—and quite

properly rejected—that argument as well. As Judge Williams explained, that trigger does apply *if* "the patent targeted in a paragraph-IV filing 'is withdrawn by the' brand manufacturer." Pet. App. 62a (quoting 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)). But that language says nothing about *when* brand manufacturers are permitted to withdraw challenged patents. As the appellate court then explained, *another* provision of the statute helps answer that question, and it makes clear that the delisting trigger—just like the forfeiture provisions to which it is linked—also requires action by the generic applicant before it can be activated. *Id.* (discussing 21 U.S.C. § 355(j)(5)(C)(ii)(I).

That key statutory provision, which Apotex inexplicably omits from its statutory appendix, is known as the "delisting counterclaim," and it was enacted at the same time Congress added the delisting forfeiture trigger. *See id.* at 57a & n.4. As the appellate court explained, "[t]he [MMA] introduced a new procedure, a counterclaim in the brand manufacturer's patent infringement suit, *through which generic companies can force brand companies to delist an improperly asserted patent.* This counterclaim provision is *the only* portion of the statute that explicitly provides for the delisting of a patent after it has been challenged in an ANDA." *Id.* at 57a (emphases added; citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)).

And reading the delisting forfeiture trigger *in pari materia* with the delisting counterclaim provision, *see Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972)); construing the language of the delisting forfeiture trigger in the context of the other

failure-to-market forfeiture provisions, *see Gutierrez v. Ada*, 528 U.S. 250, 255, (2000) ("[W]ords ... are known by their companions."); and interpreting these provisions in light of "the whole statutory text, considering the purpose and context of the statute," *Dolan v. USPS*, 546 U.S. 481, 486 (2006), the appellate court explained that there is "*not a single cogent reason* why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, *outside the counterclaim scenario identified by Teva*." Pet. App. 62a (second emphasis added).

Given the D.C. Circuit's meticulous analysis of the Act's interwoven text and structure, it is unclear how Apotex possibly can assert that the appellate court "gave no meaningful consideration to" the statute's language. Pet. 29. And with all due respect to Apotex, it is not Judge Williams's analysis of the statute that "wholly misses the point." Pet. 30. It is Petitioner's.

B. The D.C. Circuit Properly Resolved The Patent Expiry Issue.

Against this backdrop, it is easy to see why Judges Tatel, Griffith, and Kavanaugh concluded that Apotex's patent-expiry arguments warranted no more than a two-page *per curiam* disposition. Pet. App. 2a-3a. As FDA itself had concluded, Pet. App. 28a, the D.C. Circuit's prior decision in the delisting case foreclosed Apotex's claim: If brand companies cannot "'unilaterally' deprive the generic applicant of its exclusivity [by] delisting" a challenged patent, they cannot "'unilaterally' deprive the generic applicant of its exclusivity" through the simple artifice of ceasing to pay maintenance fees on such a

patent. *Id.* at 27a-28a (quoting *id.* at 35a, 63a; discussing 21 U.S.C. § 355(j)(5)(D)(i)(VI)).

Any other outcome would be absurd. It would allow brand manufacturers to do through the back door (not paying maintenance fees) precisely what the statute bars them from doing through the front door (delisting a patent), despite the lack of "*a single cogent reason* why Congress might have permitted brand manufacturers [to] unilaterally deprive the generic of its exclusivity." *Id.* at 62a (emphasis original). FDA thus did not remotely err by reading the patent expiry forfeiture trigger in the context of the broader statute and pertinent caselaw. As the appellate court explained, when "viewed in the context of the statute's incentive structure, it becomes clear that Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a [challenged] patent ... to strip the first generic applicant of the 180-day [exclusivity] period." Pet. App. 2a-3a (citing *id.* at 62a-64a); *see also Dolan*, 546 U.S. at 486 ("Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, *and consulting any precedents or authorities that inform the analysis.*") (emphasis added).

Indeed, wholly apart from its consistency with the D.C. Circuit's original decision on delisting, there are independent reasons for construing the patent-expiry trigger to prevent this sort of backdoor manipulation by brand manufacturers.

First, Hatch-Waxman's other references to patent expiration demonstrate that Congress was concerned only with *natural* patent expiration. In particular,

the statute requires Paragraph III certifications to state, at the time certification is filed, "the date on which [the listed] patent *will expire*." 21 U.S.C. § 355(j)(2)(A)(vii)(III) (emphasis added). But if brand manufacturers can cause listed patents to "expire" for Hatch-Waxman purposes by simply declining to pay maintenance fees, Paragraph III would be reduced to a guessing game: Because the brand manufacturer could quit paying those fees at *any* time, generic applicants could only speculate about what date to list. By contrast, the only date that can be stated with certainty is the date when the patent is scheduled to expire naturally, and as Paragraph III thus makes clear, that is the one that counts for purposes of the Hatch-Waxman Act.

Second, unlike patents that expire naturally, patents which "expire" for non-payment of maintenance fees don't actually die. Instead, they can be revived—in some cases "at any time"—and thereafter "shall be considered as not having expired" at all. 35 U.S.C. § 41(c)(1). There simply is no reason to think that Congress intended Hatch-Waxman exclusivity to turn on a technical form of patent expiry that may only be transient and fleeting. Indeed, that interpretation of the statute is doubly absurd. It not only would allow brand companies to *deliberately* strip the first generic's exclusivity, but would allow them to do so *negligently* as well. In particular, if the brand manufacturer inadvertently misses a fee payment and the first applicant is deemed to have forfeited exclusivity, FDA could approve all ANDAs immediately—leaving the first applicant without recourse if the patent later is revived and thus treated "as not having expired." *Id.* Congress could not possibly have

intended the patent-expiry trigger to produce such an absurdity.

Finally, the underlying rationale for divesting the first applicant of exclusivity based on patent expiration does not remotely apply where a brand manufacturer artificially pretermits a challenged patent's natural term. Long before the MMA was enacted, FDA interpreted the statute to preclude exclusivity after a patent's *natural* expiration. *See Dr. Reddy's*, 302 F. Supp. 2d at 354-55. The basis for that approach was simple. Paragraph IV challenges are designed to help expedite generic competition, *Teva v. Leavitt*, 548 F.3d at 106, but where the first applicant fails to launch before the challenged patent expires on its own, "there is no longer a need to provide an incentive to challenge it." *Dr. Reddy's*, 302 F. Supp. 2d at 354. In other words, where a Paragraph IV challenge accomplishes nothing, there is nothing to reward.

By contrast, where a patent lapses not by the mere passage of time, but rather (as here) because the first applicant's Paragraph IV certification *caused* the patentee to abandon its patent, the applicant's challenge has accomplished precisely what the statute rewards: It has opened the market to competition years earlier than would have been possible absent that challenge, and there is no reason to think that Congress intended to deprive generic applicants of their reward for achieving precisely what Paragraph IV challenges are designed to achieve.

Against this backdrop, it is clear that the patent-expiry trigger simply codified FDA's prior practice of stripping exclusivity following a patent's natural

expiration; there is no support in the text, structure, or history of the MMA for any other interpretation, as the D.C. Circuit's decision in this case recognized. Pet. App. 3a ("Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity.").

C. The D.C. Circuit's Decision Is Consistent With The Statute's Purposes.

Finally, Apotex asserts that awarding exclusivity under these circumstances harms consumers, and indeed that it only serves the brand manufacturer's interests. Pet. 32-34. Nothing could be further from the truth. As the D.C. Circuit repeatedly has explained, the Hatch-Waxman Act's 180-day exclusivity incentive exists to encourage generic companies to challenge bogus patents as quickly as possible; without that incentive, fewer patent challenges will be filed, and those that are filed will not be filed as fast. *E.g.*, Pet. App. 63a-64a.

Apotex does not deny that reality, but seeks to downplay it by asserting that "any discouraging effect such action might have on generic manufacturers would be, at best, indirect and delayed." Pet. 33. That assertion is at odds with the reality of this business. Like every other company, Teva has a limited budget—and every day it must make decisions about how to use its limited resources. So when the company is comparing two potential patent challenges head-to-head, a key question is which of those two opportunities is most

likely to yield exclusivity. After all, that reward "is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation." *Teva v. Leavitt*, 548 F.3d at 104. But if the company's analysis reveals that one of the patents at issue is held by a serial patent delister (as the record demonstrates to be the case here), the economics would change dramatically under Apotex's interpretation of the statute; as the D.C. Circuit long ago recognized, and with some understatement, "reducing the certainty of receiving a period of marketing exclusivity ... diminishes the incentive for a manufacturer of generic drugs to challenge a patent." *Ranbaxy*, 469 F.3d at 126.

Far from being "indirect and delayed," Pet. 33, the impact of Apotex's proposed interpretation would be felt every day, in virtually every ANDA filing decision—at least at any rational company. And make no mistake: Those consequences would have a significant adverse impact on the public's health and welfare over the long-run. As the D.C. Circuit once again explained in its original delisting decision:

> The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for

> generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted. As Congress deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.

Pet. App. 64a.

Teva thus earned its exclusivity here. It made enormous investments to both design around and mount a legal challenge to Merck's patent, all in the hopes of securing exclusivity and launching its products early. That effort resulted in a Paragraph IV certification so powerful that Merck simply gave up—first by delisting that patent, and then by ceasing to pay maintenance fees on a patent that Teva's Paragraph IV certification had rendered worthless.

Teva's Paragraph IV certification thereby cleared the path for generic competition to begin on these $1.5-billion-per-year drugs *four years earlier* than it would have if Teva had not challenged that patent—and thus will save consumers literally billions of dollars between April 6, 2010 (when Teva launched) and September 4, 2014 (when generics could have launched in the absence of a Paragraph IV challenge). There is no basis for thinking that Congress intended to let Merck punish Teva for delivering those savings to the public, and the D.C. Circuit thus properly affirmed the district court's decision denying Apotex's motion for preliminary injunctive relief.

CONCLUSION

For the foregoing reasons, the Petition should be denied.

JAY P. LEFKOWITZ, P.C.
KIRKLAND & ELLIS LLP
153 East 53rd Street
New York, NY 10022
(212) 446-4800
jay.lefkowitz@kirkland.com

MICHAEL D. SHUMSKY
Counsel of Record
AARON L. NIELSON
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
mshumsky@kirkland.com
anielson@kirkland.com

APPENDIX

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21 U.S.C. § 355(j)(5)(C)

(C) Civil action to obtain patent certainty.

(i) Declaratory judgment absent infringement action.

(I) In general. No action may be brought under section 2201 of title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action. If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil

action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application. For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered

terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action.

(I) In general. If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages. An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

35 U.S.C. § 41(c)

(c)

(1) The Director may accept the payment of any maintenance fee required by subsection (b) of this section which is made within twenty-four months after the six-month grace period if the delay is shown to the satisfaction of the Director to have been unintentional, or at any time after the six-month grace period if the delay is shown to the satisfaction of the Director to have been unavoidable. The Director may require the payment of a surcharge as a condition of accepting payment of any maintenance fee after the six-month grace period. If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as not having expired at the end of the grace period.

(2) A patent, the term of which has been maintained as a result of the acceptance of a payment of a maintenance fee under this subsection, shall not abridge or affect the right of any person or that person's successors in business who made, purchased, offered to sell, or used anything protected by the patent within the United States, or imported anything protected by the patent into the United States after the 6-month grace period but prior to the acceptance of a maintenance fee under this subsection, to continue the use of, to offer for sale, or to sell to others to be used, offered for sale, or sold, the specific thing so made, purchased, offered for sale, used, or imported. The court before which such matter is in

question may provide for the continued manufacture, use, offer for sale, or sale of the thing made, purchased, offered for sale, or used within the United States, or imported into the United States, as specified, or for the manufacture, use, offer for sale, or sale in the United States of which substantial preparation was made after the 6-month grace period but before the acceptance of a maintenance fee under this subsection, and the court may also provide for the continued practice of any process that is practiced, or for the practice of which substantial preparation was made, after the 6-month grace period but before the acceptance of a maintenance fee under this subsection, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced after the 6-month grace period but before the acceptance of a maintenance fee under this subsection.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC.,

Plaintiff,

v.

KATHLEEN SEBELIUS *et al.*,

Defendants.

Case No. 1:10-cv-00517-RMC

RESPONSE OF APOTEX, INC. TO SHOW CAUSE ORDER

On September 27, 2010, this Court issued an Order requiring Apotex, Inc. ("Apotex") to show cause why this case should not be dismissed for failure to state a claim. Apotex respectfully requests that the Court continue to stay the proceedings in this case for an additional limited period of time in order to allow the Supreme Court to consider the petition for writ of certiorari filed by Apotex on October 4, 2010.

As this Court is aware, in this case Apotex challenged the Food and Drug Administration's ("FDA") determination that the decision in Teva v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010), precluded the forfeiture of exclusivity based on unilateral action by the brand-name manufacturer resulting in the expiration of a patent. This Court affirmed FDA's conclusion that Teva was entitled to

exclusivity for its ANDAs referencing Cozaar or Hyzaar. Apotex appealed and filed an emergency motion to stay the commencement of Teva's exclusivity period. The Court of Appeals for the District of Columbia denied Apotex's motion and, on July 6, 2010, issued a per curiam judgment affirming this Court's decision. The mandate was filed in this Court on September 2, 2010. On October 4, 2010, Apotex filed a petition for writ of certiorari in the Supreme Court from the decision of the Court of Appeals, docketed as Apotex, Inc. v. Kathleen Sebelius, et al., No. 10-453. A copy of the petition is attached. A response to the petition currently is due on November 4, 2010.

In the event the petition is granted, the Supreme Court would be expected to address the merits of FDA's interpretation of the Hatch-Waxman forfeiture provisions. Should the petition not be granted, Apotex will then consider whether to dismiss the case, thereby rendering further proceedings unnecessary. Apotex's counsel will notify the Court promptly of any action taken by the Supreme Court.

For these reasons, Apotex respectfully requests that the Court stay further proceedings in this case pending consideration of Apotex's petition for certiorari.

Date: October 18, 2010 Respectfully submitted

Carmen M. Shepard
D.C. Bar No. 331314
Kate C. Beardsley
D.C. Bar No. 416806
Buc & Beardsley, LLP
919 18th Street, N.W.
Suite 600
Washington, D.C. 20006
(202) 736-3600

Counsel for Apotex, Inc.

FDA NEWS

Generic Line

Oct. 27, 2010 | Vol. 27 No. 21

FDA Expects More Litigation Over Generic Exclusivity

A senior FDA attorney has admitted that Teva's successful challenge of the agency's policy for withdrawing a generic-drug maker's exclusivity period caught the FDA off-guard and predicted the issue is almost certain to come up again.

The case in question took place earlier this year when the U.S. Court of Appeals for the District of Columbia Circuit overturned FDA precedent and ruled that any unilateral action by a brand-drug maker, such as delisting a patent or letting it expire, cannot be used as a means for canceling a generic-drug maker's 180-day exclusivity period.

FDA Precedent

Teva had brought the case against the FDA in an attempt to stop the agency from withdrawing its exclusivity on generic versions of Merck's hypertension drugs Cozaar (losartan potassium) and Hyzaar (hydrochlorothiazide/losartan potassium) (*Generic Line*, March 17).

Prior to that ruling, the FDA had interpreted the Medicare Modernization Act (MMA), which contains the regulations for withdrawing an exclusivity period, as stating that patent delisting or expiration were valid reasons a generic-drug maker could lose its exclusivity.

While the agency said it disagreed with the appellate court's ruling, it nonetheless approved

Teva's exclusivity, saying the court's interpretation of the MMA gave it no choice (*Generic Line*, March 31).

Since that time, numerous companies have questioned the FDA about the decision and the agency feels it is likely to arise again soon in other courts, Elizabeth Dickinson, senior counsel in the FDA's Office of Chief Counsel, said this month at the Generic Pharmaceutical Association/FDA Fall Technical Conference in Bethesda, Md.

"The outcome of that case was something that surprised FDA," Dickinson said. "It severely constrained our decisionmaking on any exclusivity that appeared to be within the control of the innovator company."

The first place the issue may arise again could be the Supreme Court. Despite Teva's exclusivity on the drugs having already expired, generic-drug maker Apotex is appealing the case to the Supreme Court, saying that how exclusivity is awarded in all future cases is at stake (*Generic Line*, Oct. 13).

"If left undisturbed, the decision will benefit brand-name manufacturers, who want nothing more than to see a first applicant win exclusivity and thereby delay full-scale competition with multiple generic manufacturers," Apotex says in its petition for a writ of certiorari filed earlier this month. "It will also richly reward the generic manufacturer who wins a race to file a Paragraph IV certification but is unable promptly to bring the generic drug to market." — David Belian

Supreme Court, U.S.
FILED
DEC 2 2 2010
OFFICE OF THE CLERK

No. 10-453

In the Supreme Court of the United States

APOTEX, INC.,

Petitioner,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

REPLY BRIEF FOR PETITIONER

CARMEN M. SHEPARD
KATE C. BEARDSLEY
Buc & Beardsley, LLP
919 18th Street, N.W.
Suite 600
Washington, D.C.
20006
(202) 736-3600

ROY T. ENGLERT, JR.*
MARK T. STANCIL
REBECCA S. LEGRAND
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP
1801 K Street, N.W.,
Suite 411
Washington, D.C. 20006
(202) 775-4500
renglert@robbinsrussell.com

**Counsel of Record*

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REPLY BRIEF FOR PETITIONER

The question presented here is undisputedly important and recurring. Respondents question only *how often* the issue will be litigated, whether the Court should await a circuit split, and whether (as Teva claims but the Federal Respondents do not) this case is moot or fatally "preliminary." None of those objections should preclude immediate review.

The D.C. Circuit's error has very harmful consequences for American consumers. And no one actually disputes that there are many more (unintended) exclusivity grants around the corner. Waiting to resolve this question is particularly ill advised, moreover, because it is highly unlikely that a circuit split would develop.

This case is not moot, and the Federal Respondents so concede—the 180-day exclusivity regime presents a classic example of the exception for issues capable of repetition, yet evading review. Teva claims otherwise but ignores the practical realities of the situation. Teva's suggestion that this case is "preliminary" is misleading; the decisions of both lower courts turned solely on the purely legal question presented.

Teva's defense of the merits fares no better. As the Federal Respondents comprehensively demonstrate, the D.C. Circuit got this very important question dead wrong.

I. Respondents Concede That The Issue Is Important And Recurring; This Court Should Not Wait To Resolve It

A. Respondents do not dispute the most important reason why review is urgently needed: The question presented is hugely important to the multi-billion-dollar generic drug industry and to consumers. See Pet. 18-24. No respondent denies that this question "controls the fate of billions of health-care dollars," Pet. 18; that "[t]he costs * * * are inevitably borne by health-care consumers," Pet. 19; or that these exclusivity provisions are "a crucial lever in the larger statutory scheme encouraging full generic competition," Pet. 23. And, as explained in detail by *amici* representing tens of millions of Americans, this question affects the health of the disturbingly large number of patients who base treatment decisions on the cost of prescription drugs. AARP Br. 5-7.

B. It is also undisputed that the issue is recurring—respondents debate only *how frequently* it will recur. Yet all agree that even a single recurrence imposes hundreds of millions of dollars in costs on consumers. In any event, Teva's assertion (at 24) that Apotex "overstates" the frequency with which this rule will be invoked is false.

No one actually disputes that "there are 27 patents for brand-name drugs—including several blockbusters—for which ANDAs including paragraph IV certifications have been filed and the challenged patent has been delisted or allowed to expire." Pet. 25. The Federal Respondents suggest (at 26-27) that "[i]t is difficult to speculate whether any of those ANDAs may generate an actual controversy," but that is not the point: Even if no litigated "contro-

versy" arises, American consumers would still risk massive (unintended) burdens for these drugs.

Teva contends (at 24) that the issue is not frequently recurring because delisting and expiration are separate issues. That is both wrong and inconsistent with Teva's past statements. After the *Teva* decision held that unilateral delisting could not result in forfeiture, FDA concluded that that holding *compelled* the same result when it was discovered that Merck had "unilaterally" allowed the '075 patent to expire. Pet. App. 27a-29a. FDA reached that conclusion *at Teva's urging*. Teva Comment Letter (Mar. 18, 2010) (FDA Docket No. 2010-N-0134).

The district court and court of appeals likewise refused to draw a distinction between delisting and expiration, Pet. App. 2a-3a, 9a—again at Teva's urging. See Teva Opp. to Motions for Preliminary Injunctive Relief 1-2 (D.D.C. Mar. 30, 2010); Teva Br. 1-2 (D.C. Cir. May 10, 2010); see also Teva Opp. to Motion to Clarify Judgment 6 (D.D.C. Mar. 23, 2010) (expiration "indistinguishable (and inseparable) from" delisting).

C. Respondents emphasize that there is no circuit split. But this Court has many times reviewed important federal statutory questions without a split. This Court recently accepted three such cases *involving the Hatch-Waxman Act—**at Teva's urging*** and over the government's contrary recommendation. *PLIVA, Inc., Teva Pharmaceuticals USA, Inc.*, et al. v. *Mensing (PLIVA)*, No. 09-993, cert. granted Dec. 10, 2010 (consolidated with Nos. 09-1039, 09-1501). As Teva aptly put it there, "[t]wo circuits may err as readily as one." Teva Supp. Br., *PLIVA*, at 6 (Nov. 23, 2010).

A split is exceedingly unlikely to develop. As the government acknowledged when seeking rehearing in the *Teva* delisting case, the D.C. Circuit's decision "could be the last word on the[se] substantial issues." *Teva* FDA Reh'g Pet. 15 (D.C. Cir. Apr. 5, 2010).

Lawsuits "regarding" the Hatch-Waxman Act are sometimes filed elsewhere, as Teva notes (at 22), but Teva does not point to a single published decision from another circuit—except for the decision discussed in the petition (at 26)—that directly addresses an award of exclusivity. Teva cites three cases involving claims that certain patents were improperly listed in the Orange Book. *Apotex, Inc.* v. *Thompson*, 347 F.3d 1335, 1343 (Fed. Cir. 2003); *aaiPharma Inc.* v. *Thompson*, 296 F.3d 227, 230 (4th Cir. 2002); *Mylan Pharm., Inc.* v. *Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001). The fourth addressed the standard for determining bioequivalence. *Schering Corp.* v. *FDA*, 51 F.3d 390, 392 (3d Cir. 1995).

The best evidence Teva can muster that exclusivity is "commonly" addressed elsewhere is a decade-old, unpublished Fourth Circuit case, *Granutec, Inc.* v. *Shalala*, Nos. 97-1873, 97-1874, 1998 WL 153410 (Apr. 3, 1998), which follows a prior *D.C. district court* decision, and a pair of district court cases that apparently were not appealed.

Moreover, the *possibility* that an exclusivity challenge could be filed outside the D.C. Circuit is likely illusory in the wake of the *Teva* decision. A first applicant like Teva is almost certain to be the first to receive tentative approval of its ANDA, which the D.C. Circuit held was necessary to make ripe Teva's challenge to FDA's anticipated exclusivity determination. A first applicant need only bring a

declaratory judgment action in the District of Columbia to benefit from the D.C. Circuit's error.

Furthermore, a subsequent applicant contemplating a lawsuit elsewhere would have to weigh the large and certain costs of bringing such a challenge against the modest potential rewards. A subsequent applicant could win only a few more months of full generic competition—fighting for market share and selling at the drastically lower profit margins resulting from full competition rather than the duopoly pricing a first applicant enjoys. The subsequent applicant's relatively modest potential rewards must also be discounted by the probabilities that no timely decision would be reached or that another court would agree with the D.C. Circuit. It is far easier for subsequent applicants to let *consumers* bear the heavy burdens exclusivity imposes—exactly what Congress sought to prevent.

The issue is fully ready for this Court's resolution. Every angle was vetted in the decision below and the *Teva* decision. The federal government has explained its view of the merits at length in this Court. Because delay would impose on consumers massive costs that Congress did not intend, the Court should not wait to decide this important issue.

II. The Case Is Not Moot, And Its Posture Is No Reason To Deny Review

A. As noted in the petition, Teva's 180-day exclusivity period has expired, but the issue is capable of repetition yet evading review. Pet. 17 n.8. The relevant exception is often invoked where, as here, the case presents an issue of significant public importance that is certain to arise again. See CHARLES

ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 3533.9 (3d ed. 2008) (citing *Honig* v. *Doe*, 484 U.S. 305, 322-323 (1988)). Similarly, the exception is frequently upheld where, as here, the question is one of pure statutory interpretation that requires no additional factual development. *Id.* § 3533.3.1; Pet. App. 43a ("the interpretations chosen by the FDA and proposed by Teva both constitute bright-line rules, impervious, so far as appears, to factual variation").

The Federal Respondents agree, explaining that "the challenged action is in its duration too short to be fully litigated" before expiration and that petitioner has a "reasonable expectation that [it] will be subject to the same action again." Gov't BIO 26 n.3 (internal quotation marks omitted). As the administrator of this regulatory regime, respondent FDA is far better positioned than Teva to assess a subsequent applicant's prospect of obtaining review before the 180-day period expires.

Teva raises mootness repeatedly (Teva BIO 1, 2, 4, 16-19) but only briefly addresses the exception for issues capable of repetition, yet evading review (*id.* at 18). Teva does not dispute that Apotex will suffer the effects of the decision below on numerous future occasions, but asserts that there is ample time for a district court, a court of appeals, and this Court all to decide a challenge before the 180-day exclusivity period expires because "there is no bar to pre-enforcement review of exclusivity issues." *Id.* at 18. That is wrong on many levels.

For starters, note Teva's careful phrasing: Teva asserts that exclusivity "*issues*" are reviewable before the 180-day period commences, but Teva does not (and cannot) contend that a proceeding challenging

an exclusivity *determination* could be completed in time. As the Federal Respondents explain (at 10), FDA's "usual practice is to render exclusivity determinations contemporaneously with granting final approval of an ANDA" (right as the 180-day fuse is lit). Teva elides that distinction by noting that the D.C. Circuit held that ***Teva's*** pre-award lawsuit as *first applicant* was ripe. Teva BIO 18. But that is not the same as holding that *subsequent applicants* could challenge a first applicant's exclusivity before a formal award is made. Teva recites the *Teva* majority's claim that "district courts 'routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval'" Teva BIO 18 (quoting Pet. App. 48a), but the cases the panel majority cited were brought by *first applicants*, and neither decision addressed ripeness. *Teva Pharm., USA, Inc.* v. *Leavitt*, 548 F.3d 103, 105 (D.C. Cir. 2008); *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120, 123 (D.C. Cir. 2006).

Indeed (although Teva fails to mention it), the district court *denied* Apotex's motion for leave to intervene in Teva's pre-award lawsuit, concluding that Apotex's interests were too speculative at that juncture. See Pet. 11 n.5; Pet. App. 103a-105a. The panel majority expressly declined to reach that question on appeal. See Pet. 11 n.6; Pet. App. 65a-66a. Teva points to no authority holding that a subsequent applicant can bring a challenge on the expectation that another generic manufacturer will, at some distant future point, be awarded exclusivity.[1]

[1] Moreover, a subsequent applicant's lawsuit would often be ripe much later than a first applicant's—even assuming that ripeness flows automatically from tentative approval—because FDA's practice is to review ANDAs in the order in which they

Even if a subsequent applicant *could* "file a declaratory judgment action" on the same timetable as a first applicant, Teva BIO 18, there is no reasonable prospect of obtaining this Court's review before the 180-day exclusivity period expires. Here, for example, barely 16 months elapsed between June 2009, when Teva filed its suit as first applicant, and the expiration of exclusivity in October 2010. That was hardly sufficient time to obtain review in the district court, court of appeals, and this Court. Indeed, the D.C. Circuit decided Teva's case March 2, 2010, and denied FDA's petition for *en banc* review May 10, 2010, leaving no realistic opportunity for a decision by this Court before exclusivity expired on October 4.[2] See, *e.g.*, *Davis* v. *FEC*, 128 S. Ct. 2759, 2769-2770 (2008) (suit filed six months before election capable of repetition, yet evading review); *Honig*, 484 U.S. at 322-323 ("adolescent student improperly disciplined for misconduct . . . will often be finished with school . . . by the time review can be had in this Court"). Thus, the example Teva points to as proof that timely review is possible actually demonstrates the opposite.

B. Teva's claim (at 19) that this case would be "a poor vehicle" because it arises from the denial of a preliminary injunction is a makeweight. The Federal Respondents do not do not even mention this as a *possible* obstacle, and for good reason.

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were filed. Thus, the very companies interested in challenging this exclusivity rule will typically be among the last to gain access to the courts.

[2] As a practical matter, a successful certiorari petition would have to have been filed by November *2009* to obtain a decision on the merits from this Court before the exclusivity period ended in October 2010.

When "there is some important and clear-cut issue of law that is fundamental to the further conduct of the case and that would otherwise qualify as a basis for certiorari, the case may be reviewed despite its interlocutory status." EUGENE GRESSMAN ET AL., SUPREME COURT PRACTICE 281 (9th ed. 2007) (citing, among many other cases, *Norfolk S. Ry.* v. *Kirby*, 543 U.S. 14, 22 (2004); *Breuer* v. *Jim's Concrete of Brevard, Inc.*, 538 U.S. 691, 694 (2003)). Likewise, review is appropriate where, as here, "the lower court's decision is patently incorrect and the interlocutory decision, *such as a preliminary injunction*, will have immediate consequences." *Ibid.* (emphasis added). The full impact of the nominally "preliminary" decision below is already being felt—generic manufacturers know that the D.C. Circuit has issued its final word on this subject.

The case technically remains pending in the district court, but *nothing has happened* below. This Court is more willing to grant review in that posture. GRESSMAN, *supra*, at 283 (citing *Kirby*, *supra* (lower court proceedings stayed pending certiorari); *Yamaha Motor Corp., U.S.A.* v. *Calhoun*, 516 U.S. 199 (1996) (same)). The district court stayed any further proceedings when Apotex appealed to the D.C. Circuit, continued that stay when Apotex explained that it had filed a certiorari petition, and directed Apotex to "file a notice of any Supreme Court action on the petition." Minute Order (Oct. 20, 2010). The outcome of this case turns on the fate of this petition.

Teva's contention (at 20-21) that this case could independently be resolved based on so-called "factual finding[s]" regarding irreparable injury is baseless. This is merely a rehash of Teva's misguided mootness argument—the premise of the exception for issues

capable of repetition, yet evading review, is that immediate relief is no longer available.

In any event, Teva misstates what the lower courts said. After concluding that the *Teva* decision foreclosed Apotex's likelihood of success on the merits, the district court held that financial injury to Apotex was legally insufficient to prove irreparable harm *but then considered Apotex's alternative argument that* ***consumers*** *would suffer irreparable harm.* Pet. App. 10a. The district court concluded that Apotex's argument "is forestalled by the Circuit's finding [in *Teva*] that the structure of the Act indicates a clear pro-consumer congressional intent to reward a first ANDA applicant." *Ibid.* Thus, the district court held that the lack of irreparable injury was compelled by the very legal rule at issue. So, too, for Apotex's contention that the public interest would be served by an injunction. *Id.* at 11a ("The argument is contrary to the teaching of *Teva*."). The D.C. Circuit affirmed based solely on its view that *Teva* precluded a likelihood of success on the merits. *Id.* at 2a. Thus, contrary to Teva's assertion, neither lower court made a relevant determination that is factual or discretionary in nature, and both agreed that the merits are all that matter.

III. As The Federal Respondents Explain, The Decision Below Is Erroneous

The Federal Respondents agree that the D.C. Circuit's "methodology, reasoning, and holding are incorrect." Gov't BIO 15. Indeed, the Federal Respondents anticipate and refute—in greater detail than space permits Apotex here—each of Teva's attempts to defend the merits. *Id.* at 16-25.

Teva claims (at 26) that *Ranbaxy* controls this question. But Teva does not (and cannot) dispute that *Ranbaxy* addressed the Hatch-Waxman Act *before* Congress added six forfeiture events to the statute's text. See Gov't BIO 21-23. Teva's complaint (at 26) that Apotex "did not challenge [*Ranbaxy*'s] holding" is bizarre: Apotex did not need to challenge *Ranbaxy* because Congress had already changed the statute.

Teva invokes the statute's "delisting counterclaim" provision (at 28), contending that it proves that Congress (silently) intended to require forfeiture only in response to a counterclaim asserted in an infringement suit. As the Federal Respondents explain (at 19-20), however, the text contains no such limitation, in stark contrast to the adjacent Subitems that expressly reference "an infringement action." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA), (BB).

In an about-face from its insistence (at 24) that expiration is not the same as delisting, Teva contends (at 29) that the "the D.C. Circuit's prior decision in the delisting case foreclosed Apotex's claim" that expiration should be treated differently. As the Federal Respondents explain, however, "the statute explicitly addresses 'Expiration of all patents,' and its text is clear." Gov't BIO 16 (quoting 21 U.S.C. § 355(j)(5)(D)(i)(VI)). Teva's quarrel is with Congress. Even if Teva had succeeded in demonstrating statutory ambiguity, that would be insufficient reason to override FDA's deference-worthy construction.

Finally, Teva defends what actually drove the D.C. Circuit's decision: the Act's perceived "incentive" structure. Teva BIO 33-36. But Teva's argument turns on the question-begging assertion that awarding exclusivity encourages generic competition. The

relevant question is: *How much* of an incentive did Congress intend to provide? Teva nowhere explains *why* a brand-name manufacturer would incur the certain loss of hundreds of millions of dollars in duopoly profits in the *hope* of temporarily discouraging *future* generic competition for *future* drugs. Nor does Teva deny that delisting often occurs in response to concerns about allegations of anticompetitive conduct. See Pet. 33-34 & n.13; Gov't BIO 24. The D.C. Circuit fundamentally "misunderstood the economic incentives at work." Gov't BIO 23.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

CARMEN M. SHEPARD
KATE C. BEARDSLEY
Buc & Beardsley, LLP
919 18th Street, N.W. Suite 600
Washington, D.C. 20006
(202) 736-3600

ROY T. ENGLERT, JR.*
MARK T. STANCIL
REBECCA S. LEGRAND
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP
1801 K Street, N.W. Suite 411
Washington, D.C. 20006
(202) 775-4500
renglert@robbinsrussell.com

**Counsel of Record*

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In the
Supreme Court of the United States

APOTEX, INC.,
Petitioner,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Respondents.

On Petition for a Writ of Certiorari To The United States Court of Appeals For The District of Columbia Circuit

BRIEF OF AARP AND CONSUMER FEDERATION OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

MEREDITH JACOB
AMERICAN UNIVERSITY
WASHINGTON COLLEGE OF LAW
4801 Massachusetts Ave., NW
Washington, DC 20016
(202) 274-4253
mjacob@wcl.american.edu

STACY CANAN
Counsel of Record
AARP FOUNDATION
LITIGATION

MICHAEL SCHUSTER
AARP

601 E Street, NW
Washington, DC 20049
(202) 434-2060
scanan@aarp.org

Counsel for *Amici Curiae*

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STATUTES

Drug Price Competition and Patent Term Restoration Act 21 U.S.C §355 ..... *ibid*

21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006) 9

21 U.S.C. § 355(j)(5)(D) 3

OTHER AUTHORITIES

H.R. Rep. No. 98-857, pt.1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 4

149 Cong. Rec. S15, 744 (daily ed. Nov. 24, 2003) (Sen. Schumer) 4

149 Cong. Rec. S15, 884 (daily ed. Nov. 25, 2003) (Sen. Kennedy) 4

AARP, Rx Watchdog Report, May 2010, *available at* http://www.aarp.org/health/drugs-supplements/rx_watchdog.html 2

Inderjit S. Bansal, et al., *Evergreening – A Controvercial Issue in Pharma Milieu*,14 J. Intell. Prop. Rights 299, 301 (2009) 9

Linda L. Barrett, Ph.D., AARP, *Prescription Drug Use Among Midlife and Older Americans* (2005), *available at* assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf 1

Becky A. Briesacher, et al., *Patients At-Risk for Cost-Related Non-Adherence: A Review of the Literature*, 22 J. Gen. Internal Med. 864 (2007) 6

Competition in the Pharmaceutical Industry: Testimony before the S. Comm. on the Judiciary, 108th Cong. (June 17, 2003) (statement of Timothy J. Muris, Chairman, FTC) *available at* http://ftc.gov/os/2003/06.030617pharmtestimony.htm 5

William Encinosa, et al., *Does Prescription Drug Adherence Reduce Hospitalizations and Costs? The Case of Diabetes*, 22 ADVANCES HEALTH ECON. SERVICES RES. 151 (2010) 7

Families USA, Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010 at 2 (July 2000) 1

FDA, *Generic Competiton and Drug Prices*, *available at* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm, (last visited Nov. 1, 2010) 8

FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010) 5, 8

FTC Study: Generic Drug Entry Prior to Patent Expiration: Testimony before S. Comm. on the Judiciary, 108th Cong. (June 17, 2003) (Daniel Troy, Chief Counsel, FDA)..... 10

FTC, *Generic Drug Entry Prior to Patent Expiration* (July 2002)..... 10

Federal Trade Commission, Wrongful "Orange Book" Listing Raises Flag with FTC (April 23, 2002) *available at*, http://www.ftc.gov/opa/2002/04/biovailtiazac.shtm..... 9

Ben Hirschler, *Drugmakers face $140 bln patent "cliff"*, Reuters (May 1, 2007) *available at* http://www.reuters.com/article/id USL01121531200705O2 11

Jacob Kurlander, et al., *Cost-Related Non-Adherence to Medications Among Patients with Diabetes and Chronic Pain: Factors Beyond Finances*, 32 Diabetes Care 2143 (2009) 6

Memorandum for Federal Trade Commission as *Amicus Curiae* In Opposition to Defendant's Motion to Dismiss, *In re: Buspirone Patent Litigation*, 185 F.Supp.2d 363 (S.D.N.Y). 2002), (No. 1410) 10

National Institute for Healthcare Management, A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace (June 2002) 4

Haim Reuveni, et al., *The Effect of Drug Co-Payment Policy on the Purchase of Prescription Drugs for Children with Infections in the Community*, 62 Health Pol'y 1 (2002) 6-7

Michael Soskol, et al., *Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost*, 42 Med. Care 521 (2005) 7

Yuing Zhang, et al., *Ambulatory Antibiotic Use and Prescription Drug Coverage in Older Adults*, 170 Archives Internal Med. 1308 (2010) 7

INTERESTS OF *AMICI CURIAE*[1]

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable prescription medication is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010 at 2 (July 2000). Significantly, in a 2005 AARP survey, one in four Americans 50+ who took a prescription drug in the past five years said they did not fill a prescription written by their doctor in the past two years. Cost was reported as the main deterrent. Linda L. Barrett, Ph.D., AARP, *Prescription Drug Use Among Midlife and Older Americans* (2005), *available at*

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[1] In accordance with Supreme Court Rule 37.6, *Amici Curiae* state that: (1) no counsel to a party authored this brief, in whole or in part; and (2) no person or entity, other than *amici*, their members and counsel have made a monetary contribution to the preparation or submission of this brief. Parties were timely informed of the intent to file this *amici* brief, and the written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

assets.aarp.org/rgcenter/health/rx_midlife_plus.pdf. Since prescription drug spending has skyrocketed over the last decade and a half, and national health expenditures on prescription drugs have quadrupled, AARP advocates for broader access to prescription drugs and lower prescription drug costs for consumers. *See e.g.,* AARP, Rx Watchdog Report, May 2010, *available at* http://www.aarp.org/health/drugs-supplements/rx_watchdog.html.

Consumer Federation of America ("CFA") is a non-profit organization founded in 1968 to advance consumer interests through research, education and advocacy. CFA is comprised of more than 280 state and local affiliates representing consumer, senior citizen, low income, labor, farm, public power and cooperative organizations. CFA represents consumer interests before federal and state regulatory and legislative agencies and participates in court proceedings. CFA has been particularly active on antitrust issues affecting health care, medical device, and high technology industries in which exclusive dealing and other practices by dominant firms can have significant consequences for consumers.

REASONS FOR GRANTING THE PETITION

SUMMARY OF ARGUMENT AND INTRODUCTION

Many patients face a daily struggle to pay for their prescribed medicines. This endangers their health and reduces their quality of life. When patients do not take prescribed medication because of cost, attendant health complications and the worsening of chronic disease stress the healthcare system as a whole.

The DC Circuit's decision below narrowly interpreting 21 U.S.C. § 355(j)(5)(D), the forfeiture provision of the 2003 Medicare Modernization Act amendments ("2003 MMA amendments") to the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), 21 U.S.C. §355 (1994), extends prescription drug market exclusivity, which in turn keeps the cost of prescription drugs artificially high in contravention to the purpose of the 2003 MMA amendments and the Hatch-Waxman Act.

For Hatch-Waxman and the MMA to provide the intended benefit to patients, there must be the correct balance of both incentives for generic challenges, and also open competition among generics. In this case the D.C. Circuit's decision is in sharp contrast with the language and purpose of the statute. The correct interpretation of the statute has a concrete impact on the health of patients and delayed resolution of this issue will result in

permanent harm to those patients in the form of increased medical cost and sub-optimal care. *Amici* therefore urge the Court to grant the Petition for *Writ of Certiorari* in this case.

ARGUMENT

I. THE DC CIRCUIT'S NARROW INTERPRETATION OF THE FORFEITURE PROVISION REDUCES GENERIC DRUG COMPETITION.

The forfeiture provision in the 2003 MMA amendments was not conceived merely as an elaborate method of determining privileges and priority among generic drug makers in a vacuum, but rather as a method to ensure the vitality of the generic drug industry, and increase competition among generic drug makers. Congress recognized that a thriving competition among generic drug makers drives down drug prices and improves the health care options available in the United States. *See* H.R. Rep. No. 98-857, pt.1 (1984), reprinted in 1984 U.S.C.C.A.N. 2647; *See also,* National Institute for Healthcare Management, A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace (June 2002). Hatch-Waxman and the 2003 MMA amendment were intended to speed generic entry into the market because the availability of generic drugs decreases the costs of medicine and allows more patients to get treatment. *See* 149 Cong. Rec. S15, 744-46 (daily ed. Nov. 24, 2003) (Sen. Schumer); 149 Cong. Rec. S15, 884 (daily ed. Nov. 25, 2003) (Sen. Kennedy).

While the D.C. Circuit raises the specter of a brand name drug undercutting the ability of a generic to earn exclusivity by the brand manufacturer's strategic withdrawal of a patent from the Orange Book, the record does not support such contrivance. Indeed, reported abuses to date have involved collusion between brand name and generic drug makers entering agreements to delay entry of generics. The FTC has reported extensively on "pay-for-delay" and generic drug "parking" of 180 day exclusivity as a way for the brand manufacturer and the first-to-file generic to reap monopoly/duopoly benefits. *See* FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010) (hereinafter "Pay-for-Delay"); *Competition in the Pharmaceutical Industry: Testimony before the S. Comm. on the Judiciary*, 108th Cong. (June 17, 2003) (statement of Timothy J. Muris, Chairman, FTC) *available at* http://www.ftc.gov/os/2003/06030617pharmtestimony.htm.

II. OPEN GENERIC DRUG COMPETITION AND LOWER PRICES AFFECT PATIENT OUTCOMES AND PUBLIC HEALTH.

A. Drug Prices Matter to Patient Outcomes.

For many patients, paying for their medicines is a daily struggle. For patients without insurance, the presence of a generic on the market may dictate whether they can afford treatment. Even for patients with insurance, the difference between a lower generic co-payment and a higher brand name

one affects the choices patients make. *See* Becky A. Briesacher, et al., *Patients At-Risk for Cost-Related Non-Adherence: A Review of the Literature*, 22 J. Gen. Internal Med. 864 (2007). For many older patients on multiple maintenance medications, even with insurance, co-payments can stress budgets pegged to a fixed income.

With no other choices available to them, many patients skip doses, split pills, and discontinue medications without consulting their physician, even in the case of serious illness. Jacob Kurlander, et al., *Cost-Related Non-Adherence to Medications Among Patients with Diabetes and Chronic Pain: Factors Beyond Finances*, 32 Diabetes Care 2143 (2009). The presence of a low-cost generic on the other hand may be the difference between a patient taking a prescribed medication, and that same patient skipping doses or choosing not to fill the prescription at all. *See Briesacher*, supra note 4 (finding that 32% of U.S. seniors took less medicine than prescribed because of cost, with reducing dosage more common than forgoing the prescription entirely.)

Patient compliance is a central issue in keeping hospital re-admissions down, reducing antibiotic resistance, and other serious health consequences. Studies of drug co-payment plans and drug pricing show that patients make cost-based decisions to forego treatment, even when facing acute infections for which antibiotics have been prescribed. This has been documented in both older patients and low-income patient populations. *See* Haim Reuveni, et

al., *The Effect of Drug Co-Payment Policy on the Purchase of Prescription Drugs for Children with Infections in the Community*, 62 Health Pol'y 1 (2002); Yuing Zhang, et al., *Ambulatory Antibiotic Use and Prescription Drug Coverage in Older Adults*, 170 Archives Internal Med. 1308 (2010).

Thus for both patients and public health systems, the cost of delayed generic access is twofold. First there is the increased cost of medication when open generic competition is not available. Second, non-adherence leads to medical complications that require advanced care, such as hospitalization. Diabetes presents one such case where proper medical management can prevent costly hospitalization, and even dialysis. *See* William Encinosa, et al., *Does Prescription Drug Adherence Reduce Hospitalizations and Costs? The Case of Diabetes*, 22 Advances Health Econ. Services Res. 151 (2010); *see also* Michael Soskol, et al., *Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost*, 42 Med. Care 521 (2005) (finding that the cost of medication adherence was "more than offset" by the reduced cost of disease-related medical costs). Towards this end, the price of medicines is vital to patients and public health. Further, high prices of medicines and medical care lead to other destructive practices such as medicine sharing and the over-use of emergency care.

B. Generic Drug Competition Dramatically Lowers Prices.

Open generic competition reliably drives down medicine prices. A Federal Trade Commission ("FTC") study on the effects of generic competition found that "in a mature generic market, generic prices are, on average 85% lower than pre-entry branded drug price." *Pay-for-Delay*, supra note 3 at 8. This is significant; the majority of generic savings come only when there is open competition. In the cases where there is only one generic, either as an authorized generic or through a Paragraph IV grant of exclusivity, a substantial price drop is rarely seen. A five year FDA study on the effect of generic competition on drug prices found that a sole generic entry into the market only reduced prices 6%, while the most aggressive competition yielded a 96% price reduction. The effect is seen as the number of generic entries increases, with more generic competition consistently yielding lower prices. FDA, *Generic Competition and Drug Prices, available at* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm (last visited Nov. 1, 2010).

One hundred and eighty day exclusivity is a valuable tool to encourage brand competition, but there is a real price to pay. The decision to apply it is not, nor did Congress intend it to be, an absolute reward for a generic drug manufacturer when a forfeiture provision is triggered, as in the instant case.

III. RESOLVING THIS UNCERTAINTY IS URGENT BECAUSE OF THE HIGH NUMBER OF BLOCKBUSTER PATENT EXPIRATIONS EXPECTED IN THE NEAR FUTURE.

As discussed in the petition for *certiorari*, brand name medicines are often protected by multiple patents in the Orange Book. A given drug is usually protected not only by a core patent, but also by ancillary patents on methods of use, different isomeric forms, and variations such as extended release formulas. *See Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1374 (2002); 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006); and *see* Inderjit S. Bansal, et al., *Evergreening – A Controvercial Issue in Pharma Milieu*, 14 J. Intell. Prop. Rights 299, 301 (2009). Pharmaceutical companies use these ancillary patents to extend the term of protection for a drug beyond the twenty-year period contemplated by patent law.

Past complaints by the FTC against pharmaceutical manufacturers have included explicit allegations that manufacturers wrongfully listed patents in the Orange Book in order to block generic competition to their products. *See* Press release, Federal Trade Commission, Wrongful "Orange Book" Listing Raises Flag with FTC (April 23, 2002) *available at* http://www.ftc.gov/opa/2002/04/biovailtiazac.shtm ("acquiring an exclusive patent license and wrongfully listing that patent" in the "Orange Book" in order to "block[] generic competition to its branded drug..."). FTC testimony

in 2003 addressed the question of "whether certain 'later-listed' patents or inappropriate patent submissions by the sponsors of innovator drug products have resulted in the delay of generic drug approvals." *FTC Study: Generic Drug Entry Prior to Patent Expiration: Testimony before S. Comm. on the Judiciary*, 108th Cong. (June 17, 2003) (Daniel Troy, Chief Counsel, FDA). The FTC argued that pharmaceutical companies attempted to gain market monopoly through falsely asserting that a new patent exists "despite knowing that the patent does not, in fact, claim the drug." Memorandum for Federal Trade Commission as *Amicus Curiae* In Opposition to Defendant's Motion to Dismiss, *In re: Buspirone Patent Litigation*, 185 F.Supp.2d 363 (S.D.N.Y.) 2002, (No. 1410) ("In essence, BMS claims that a pharmaceutical company is at liberty, as a matter of antitrust law, to monopolize a market by means of falsely asserting to the FDA that a new patent claims its approved branded drug, despite knowing that the patent does not, in fact, claim the drug and hence does not meet the statutory criteria for listing in the Orange Book."). This strongly suggests that these ancillary patents are often of inferior quality and will not withstand judicial scrutiny. Supporting this conclusion, a 2002 study by the FTC showed that generic companies prevail in the strong majority of challenges under paragraph IV. *See* FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (July 2002) ("Generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute. The rate at which the U.S. Court of Appeals for the Federal Circuit reversed district court

decisions of patent invalidity and non-infringement for drug products in this study was 8 percent.").

Because these ancillary patents are used to extend the marketing exclusivity for a brand name drug, they are often the subject of paragraph IV challenges, and subject to withdrawal or delisting by the brand manufacturer near the end of a drug's market exclusivity.

In the immediate future, the industry faces an unprecedented number of patent expirations for blockbuster drugs currently prescribed to millions of patients. These conditions create heightened urgency to correctly interpret and apply the statutory scheme set out in the MMA and Hatch-Waxman.

GlaxoSmithKlein, AstraZeneca, Merck, and Pfizer, among others, will lose monopoly rights to at least one major drug before 2012. *See* Ben Hirschler, *Drugmakers face $140 bln patent "cliff"*, Reuters (May 1, 2007) *available at* http://www.reuters.com/article/idUSL01121531200705O2. By 2016, patent protection will expire on drugs accounting for $140 billion in sales. *See id.* This suggests that there will be an unprecedented number of challenges in the coming years by generic manufacturers attempting to acquire 180 days of exclusive access to the markets for these drugs. As consumers are about to reap the rewards of cheaper generic alternatives, it is critical that this issue be addressed to ensure that those consumers are not needlessly denied those benefits.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

November 4, 2010

Respectfully submitted,

Meredith Jacob
American University
Washington College of Law
4801 Massachusetts Ave., NW
Washington, DC 20016
(202) 274-4253
mjacob@wcl.american.edu

Stacy Canan
Counsel of Record
AARP Foundation
Litigation

Michael Schuster
AARP

601 E Street, NW
Washington, DC 20049
(202) 434-2060
scanan@aarp.org

Counsel for *Amici Curiae*